

1 UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

4 IN RE: NATIONAL)
5 PRESCRIPTION) MDL No. 2804
6 OPIATE LITIGATION)
7 Case No.
8) 1:17-MD-2804
9)
10 THIS DOCUMENT RELATES) Hon. Dan A.
11 TO ALL CASES) Polster
12)

13 FRIDAY, MAY 17, 2019

14 HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
15 CONFIDENTIALITY REVIEW

16 - - -

17 Videotaped deposition of Thomas
18 Prevoznik, Volume III, held at the offices of
19 WILLIAMS & CONNOLLY LLP, 725 Twelfth Street,
20 NW, Washington, DC, commencing at 8:10 a.m.,
21 on the above date, before Carrie A. Campbell,
22 Registered Diplomate Reporter and Certified
23 Realtime Reporter.

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1 VIDEOGRAPHER: We are now on
2 the record. My name is Dan Lawlor.
3 I'm a videographer with Golkow
4 Litigation Services.

5 Today's date is May 17, 2019,
6 and the time is 8:10 a.m.

7 This video deposition is being
8 held in Washington, DC, in the matter
9 of National Prescription Opiate
10 Litigation, MDL Number 2804.

11 The deponent is Thomas
12 Prevoznik.

13 Counsel will be noted on the
14 stenographic record.

15 The court reporter is Carrie
16 Campbell and will now swear in the
17 witness.

18
19 THOMAS PREVOZNIK,
20 of lawful age, having been first duly sworn
21 to tell the truth, the whole truth and
22 nothing but the truth, deposes and says on
23 behalf of the Plaintiffs, as follows:

24 (Prevoznik Plaintiff Exhibit
25 P17 marked for identification.

1 EXAMINATION (continued)

2 QUESTIONS BY MR. FARRELL:

3 Q. Good morning.

4 A. Good morning.

5 Q. Welcome back to day three of
6 your deposition, Mr. Prevoznik.

7 I'll remind you or let me ask
8 you to recall that today you'll be testifying
9 on behalf of the United States Drug
10 Enforcement Administration, the DEA, on
11 subject matters that have been requested in
12 this litigation.

13 Continuing the line of
14 discussion, I'm going to -- I have marked,
15 premarked, and am showing you Plaintiff's
16 Exhibit 17, and the first thing I'd like to
17 do is I'd like to direct your attention to
18 the bottom right-hand corner.

19 And you see the numbers
20 US-DEA-00025656?

21 A. Yes, I do.

22 Q. I'll represent to you that's a
23 Bate stamp number provided by the Department
24 of Justice. And what I wanted to do was to
25 lay a little foundation on the documents that

1 bear such a Bate stamp.

2 The DEA has produced through
3 the United States Department of Justice more
4 than 6,000 documents in this litigation
5 spanning more than 26,000 pages.

6 Do you acknowledge as the
7 representative of the DEA that all such
8 documents bearing the US DEA Bates stamp are,
9 in fact, true and accurate photocopies of
10 documents in the possession, custody and
11 control of the DEA?

12 A. Yes.

13 Sorry.

14 MR. FINKELSTEIN: Tom. Scope.

15 You can answer.

16 MR. EPPICH: Objection.

17 Foundation.

18 THE WITNESS: Yes.

19 QUESTIONS BY MR. FARRELL:

20 Q. And the DEA is, in fact, the
21 custodian of these documents?

22 MR. FINKELSTEIN: Scope.

23 MR. O'CONNOR: Objection.

24 Foundation.

25 THE WITNESS: Yes.

1 QUESTIONS BY MR. FARRELL:

2 Q. So as the DEA, you acknowledge
3 that the documents produced by the Department
4 of Justice bearing this Bates stamp number
5 are documents that come from the DEA which
6 are held in the usual course of the regularly
7 conducted activity of the DEA?

8 MR. FINKELSTEIN: Scope.

9 MR. EPPICH: Objection.

10 Foundation.

11 MR. O'CONNOR: Objection.

12 MR. FINKELSTEIN: You can
13 answer.

14 THE WITNESS: Yes.

15 QUESTIONS BY MR. FARRELL:

16 Q. All right. Moving to the first
17 document, P17.

18 Do you recognize this document?

19 And this isn't Jeopardy. This document
20 actually was included in your reliance
21 materials.

22 But could you tell the jury
23 what this document is?

24 A. This document is a report based
25 off of a meeting, a conference that was held

1 for manufacturers and wholesalers that we
2 sponsor.

3 Q. And what is the date?

4 A. April 7th through the 9th,
5 1987.

6 Q. I'm going to have you flip to
7 the very back page of the four-page document
8 that was provided by the DEA, and you'll see
9 there that there is a provision that talks
10 about excessive order monitoring program.

11 Is this a document that was
12 prepared by the DEA?

13 MR. EPPICH: Objection.

14 Foundation.

15 THE WITNESS: Yes.

16 QUESTIONS BY MR. FARRELL:

17 Q. So when you're reading this on
18 behalf of the DEA, the very first sentence
19 referenced the fact that the program was
20 chaired by Ronald Buzzeo.

21 Does the DEA know Ronald
22 Buzzeo?

23 A. Yes.

24 Q. Who is Ronald Buzzeo?

25 A. He was a senior manager within

1 DEA back at this time. I don't know what his
2 specific title was back then.

3 Q. You'll see that in the
4 provision on the demonstrative that I've
5 highlighted, the last sentence of the first
6 paragraph, would you please read that into
7 the record?

8 MR. FINKELSTEIN: Starting with
9 "another area" or somewhere else?

10 MR. FARRELL: No, right above
11 it. The last sentence of that first
12 paragraph.

13 THE WITNESS: The NWA?

14 QUESTIONS BY MR. FARRELL:

15 Q. Yes, sir.

16 A. "The NWA system, for example,
17 provide an excellent look-back, or trend
18 system, but the ability to identify one-time
19 suspicious orders should not be overlooked as
20 an element of a program."

21 Q. Is that consistent with the
22 guidance the DEA has provided manufacturers
23 and distributors regarding their obligations
24 under the Controlled Substances Act and the
25 regulations promulgated by the DEA?

1 MR. EPPICH: Object to form.

2 MS. MAINIGI: Objection.

3 THE WITNESS: Yes.

4 QUESTIONS BY MR. FARRELL:

5 Q. Okay. So when we're talking
6 about the NWDA system, we have previously put
7 into the record the NWDA, but recently we've
8 gotten another document, another version of
9 the document, and I'm going to have it marked
10 as P18.

11 (Prevoznik Plaintiff Exhibit
12 P18 marked for identification.)

13 QUESTIONS BY MR. FARRELL:

14 Q. So this is identical to the
15 document that has been circulated in
16 litigation before, but as you recall from the
17 last time we met, there were two pages at the
18 back of this document that were missing.

19 So the first thing I want to do
20 is note that -- you see at the bottom
21 right-hand corner there is a US DEA Bates
22 stamp of 00026139?

23 A. Correct.

24 Q. And what I'd like to do is I'd
25 like to address your attention to what is

1 page 7 of this policy.

2 And again, building on the
3 testimony from the previous two days without
4 repeating it, I'm going to show you the
5 bottom right-hand corner is US-DEA-00026146,
6 and I'd ask you to read Roman Numeral IX into
7 the record.

8 A. "Single suspicious orders.
9 Single orders of unusual size or deviation
10 must be reported immediately. The submission
11 of a monthly printout of after-the-fact sales
12 will not relieve a registrant from the
13 responsibility of reporting these single
14 excessive or suspicious orders. DEA has
15 interpreted 'orders' to mean prior to
16 shipment."

17 Q. So my question to you is, is
18 this consistent with the guidance provided by
19 the DEA to wholesalers and distributors?

20 MR. EPPICH: Objection.

21 Foundation.

22 MS. MAINIGI: Objection.

23 Foundation.

24 THE WITNESS: Yes.

25

1 QUESTIONS BY MR. FARRELL:

2 Q. Is this consistent with the
3 guidance provided by Ronald Buzzeo at the
4 San Antonio conference hosted by the DEA?

5 MR. EPPICH: Objection.

6 Foundation. Calls for speculation.

7 MR. FINKELSTEIN: Scope.

8 You can answer, if you know.

9 MS. MAINIGI: Scope.

10 THE WITNESS: Looking at the
11 two, yes.

12 QUESTIONS BY MR. FARRELL:

13 Q. Now, I'm going to have you turn
14 to the NWDA policy and the comments that come
15 from the DEA that were previously discussed,
16 but I'm going to reference the Bates stamp
17 numbers in the bottom right-hand corner,
18 including US-DEA-00026148. It's dated
19 April 24, 1984.

20 Have you found it?

21 A. Yes.

22 Q. Okay. And again, we've already
23 established the foundation for this, but
24 we'll do it again.

25 Do you recognize this document?

1 MR. EPPICH: Object to the
2 form.

3 THE WITNESS: Yes.

4 QUESTIONS BY MR. FARRELL:

5 Q. Okay. As the DEA, can you tell
6 me on page 2 who the author of this document
7 is?

8 A. Thomas Gitchel.

9 Q. And who is Thomas Gitchel?

10 A. He was -- at this point he was
11 the acting chief of diversion operations.

12 Q. Of the DEA?

13 A. Of the DEA.

14 Q. Okay. And I've highlighted
15 down -- a particular provision for emphasis
16 to build on the previous two days' testimony.
17 Beginning with "As previously discussed,"
18 could you read that provision into the
19 record?

20 A. "An after-the-fact computer
21 printout of sales data does not relieve a
22 registrant of its responsibility to report
23 excessive or suspicious orders when
24 discovered."

25 Q. Is this consistent with the

1 guidance the DEA has provided to the
2 wholesalers and manufacturers of prescription
3 opioids?

4 MR. EPPICH: Object to form.

5 THE WITNESS: Yes.

6 QUESTIONS BY MR. FARRELL:

7 Q. I'm going to show you -- which
8 is the last page of this document. And
9 you'll see in the bottom right-hand corner is
10 US-DEA-00026150. It has the stamp of May 16,
11 1984.

12 And I would ask do you
13 recognize this document?

14 A. Yes.

15 Q. And what is it?

16 A. It's a letter from Mr. Gitchel,
17 again, from DEA to the National Wholesales
18 Druggists' Association.

19 Q. And again, I've highlighted for
20 your convenience the last sentence of the
21 first paragraph beginning with the word
22 "however," and I'd ask for you to read it
23 into the record.

24 A. "However, I want to make it
25 clear that the submission of a monthly

1 printout of after-the-fact sales will not
2 relieve a registrant from the responsibility
3 of reporting excessive or suspicious orders.
4 DEA has interpreted 'orders' to mean prior to
5 shipment."

6 Q. Is this consistent with the
7 guidance the DEA has provided to wholesalers
8 and manufacturers of prescription opioids?

9 MS. MAINIGI: Objection.

10 MR. EPPICH: Objection.

11 THE WITNESS: Yes.

12 (Prevoznik Plaintiff Exhibit
13 P19 marked for identification.)

14 QUESTIONS BY MR. FARRELL:

15 Q. The next document I'm going to
16 have marked as Plaintiff's Exhibit 19, it
17 bears Bate stamp US-DEA-00025683. I'll give
18 you a second to take a look at it, but I'm
19 assuming you're familiar with this document.

20 Do you see the bottom
21 right-hand corner, it bears the Bates stamp
22 US DEA?

23 A. Yes.

24 Q. Do you recognize this document?

25 A. Yes.

1 Q. What is it?

2 A. It's a letter from Mr. Buzzeo,
3 who was at that point the deputy director of
4 diversion control, to Walgreens.

5 Q. And what's the date?

6 A. December 27, 1988.

7 Q. Okay. Would you read the first
8 sentence that's emphasized on your monitor?

9 A. "References made to our
10 November 4, 1988 meeting regarding a proposed
11 system of detecting and reporting excessive
12 orders."

13 Q. All right. If you look down at
14 the -- you can read the rest -- the first
15 paragraph, but I'm going to direct your
16 attention to the beginning of the second
17 paragraph where it states, "The Drug
18 Enforcement Administration supports the
19 effort by the Walgreen Company to provide a
20 uniform reporting procedure for its
21 warehouses."

22 Do you see that?

23 A. Yes.

24 Q. In fact, is this consistent
25 that the DEA has encouraged wholesalers and

1 distributors of prescription opioids to adopt
2 uniform reporting procedures?

3 MR. EPPICH: Object to form.
4 Foundation.

5 THE WITNESS: Yes.

6 QUESTIONS BY MR. FARRELL:

7 Q. All right. What I'm going to
8 emphasize is the very last two sentences that
9 begin with "the submission."

10 Do you see that provision?

11 A. Yes.

12 Q. And I'd ask you to read that
13 into the record.

14 A. "The submission of a monthly
15 printout of after-the-fact sales does not
16 relieve the registrant of the responsibility
17 of reporting excessive or suspicious orders.
18 These regulations require that a registrant
19 maintain a system to detect excessive orders
20 rather than sales of controlled substances."

21 Q. Is this statement consistent
22 with the guidance provided by the DEA to
23 wholesale distributors and manufacturers of
24 prescription opioids?

25 MR. EPPICH: Object to form.

1 Foundation.

2 THE WITNESS: Yes.

3 QUESTIONS BY MR. FARRELL:

4 Q. Now, not only being consistent,
5 this, in fact, is the actual statement
6 provided by the DEA to Walgreens, agreed?

7 MR. EPPICH: Object to form.

8 Foundation.

9 THE WITNESS: Yes.

10 QUESTIONS BY MR. FARRELL:

11 Q. Would you agree with me that
12 since at least 1988, Walgreens has been on
13 notice from the DEA that if they rely upon
14 after-the-fact sales to comply with the
15 Controlled Substances Act and the regulations
16 promulgated by the DEA, that they may not be
17 in compliance with federal law?

18 MR. EPPICH: Object to form.

19 Foundation.

20 THE WITNESS: Yes.

21 QUESTIONS BY MR. FARRELL:

22 Q. If any of the wholesale
23 distributors or manufacturers of prescription
24 opioids rely upon after-the-fact reporting of
25 excessive orders to -- as the system they

1 designed under 1301.74(b), is that sufficient
2 to comply with federal law?

3 MR. EPPICH: Object to form.
4 Foundation.

5 MR. MAHADY: Objection. Vague.

6 THE WITNESS: Could you please
7 repeat it?

8 QUESTIONS BY MR. FARRELL:

9 Q. If any distributor of
10 prescription opioids relies upon
11 after-the-fact sales reporting as the full
12 scope of its compliance with 1301.74(b), does
13 the DEA believe that it's sufficient to
14 satisfy the obligations under federal law?

15 MS. MAINIGI: Objection.

16 MR. EPPICH: Object to form.
17 Foundation. Vague.

18 THE WITNESS: No.

19 QUESTIONS BY MR. FARRELL:

20 Q. If any expert witness in this
21 litigation argues that after-the-fact sales
22 are sufficient to comply with federal
23 regulations, is the expert witness right or
24 wrong?

25 MS. MAINIGI: Objection to

1 form. Scope.

2 MR. EPPICH: Objection.

3 THE WITNESS: They would be
4 wrong.

5 (Prevoznik Plaintiff's Exhibit
6 P20 marked for identification.)

7 QUESTIONS BY MR. FARRELL:

8 Q. The next document I'm going to
9 have marked is P20.

10 And I'll direct your attention
11 to the bottom right-hand corner with the
12 Bates stamp US-DEA-00026154. It has the
13 stamp of December 8, 1993, and I'm going to
14 ask you if you recognize this document.

15 A. Yes.

16 Q. What is this document?

17 A. This is an internal document
18 from Gene Haislip, our director of Office and
19 Diversion Control DEA, to the SAC, or special
20 agent in charge, of our Dallas field
21 division.

22 Q. Okay. Is this the type of
23 document that the DEA keeps in the course of
24 its regularly conducted activity?

25 A. Yes.

1 Q. Okay. Was this record made at
2 or near the time of someone with knowledge
3 about the conversations therein?

4 MR. FINKELSTEIN: Scope.

5 MR. EPPICH: Objection.

6 MS. MAINIGI: Objection.

7 Scope. Form. Foundation.

8 MR. FINKELSTEIN: Scope.

9 You can answer.

10 THE WITNESS: Yes.

11 QUESTIONS BY MR. FARRELL:

12 Q. It appears, to give you the
13 short form of it, that this is a discussion
14 between Mr. Haislip and a Mr. Jordan.

15 Who is Mr. Haislip?

16 A. He was the director of the
17 Office of Diversion Control for DEA.

18 Q. What does that mean?

19 A. He's in charge of the diversion
20 program within DEA.

21 Q. So in the ranking, in my mind,
22 where does that put him in the rank?

23 A. He's the top.

24 Q. And then Mr. Jordan. Who is
25 Mr. Jordan?

1 A. He's the special agent in
2 charge of our Dallas field division, so he's
3 the head of the entire DEA Dallas field
4 division.

5 Q. And how many different field
6 divisions are there?

7 A. At this time or now?

8 Q. At this time.

9 If the DEA remembers in its
10 official capacity.

11 A. Yeah, I don't -- I'd be
12 speculating. I think it was 20.

13 Q. 20?

14 A. We're now up to 23.

15 Q. And how many people were in the
16 cog between the field division boss and the
17 director?

18 Is there two levels, three
19 levels of reporting or direct?

20 MR. FINKELSTEIN: Vague as to
21 time.

22 QUESTIONS BY MR. FARRELL:

23 Q. In 1993.

24 A. I'm not sure I understand what
25 you're asking.

1 Q. I'm just trying to figure out
2 this communication.

3 Is it normal for a field
4 division boss to be communicating directly
5 with the director?

6 A. Yeah. I mean, they're both
7 SESEs, so they're both --

8 Q. Okay.

9 A. They're both the same level.

10 Q. They're the same rank?

11 A. Yes.

12 Q. All right. So it appears that
13 this is a discussion on whether or not the
14 DEA is going to provide guidelines on
15 suspicious order reporting.

16 Do you see that?

17 A. Yes.

18 Q. And I'd ask you to begin
19 reading, as you see in the second paragraph,
20 their discussion 1301.74(b).

21 Do you see that?

22 A. Yes.

23 Q. Now, this is in 1993.

24 Is 1301.74(b) the same in 1993
25 as it is today?

1 A. Yes.

2 Q. And is it the same in all
3 meaningful ways to what it looked like when
4 it was enacted in 1971?

5 A. Yes.

6 Q. So beginning with
7 "Section 1301.74(b)," could you read the next
8 sentence?

9 A. "1301.74(b) of Title 21 of the
10 Code of Federal Regulations clearly places
11 the responsibility for designing and
12 operating a system to identify suspicious
13 orders of controlled substances on the
14 registrant. Implicit in this regulation is
15 the idea that the registrant should not
16 merely be accumulating data on what appear to
17 be excessive purchases for eventual
18 submission to DEA but rather that the system
19 be monitored so that any such orders will be
20 apparent to the registrant so that they -- so
21 that they can be reported to DEA upon
22 discovery and, whenever possible, before the
23 order is shipped."

24 Q. Is this consistent with the
25 guidance provided by the DEA to wholesale

1 distributors and manufacturers of
2 prescription opioids?

3 MR. EPPICH: Object to form.
4 Foundation.

5 THE WITNESS: Yes.

6 QUESTIONS BY MR. FARRELL:

7 Q. Now, again, we're going to be
8 talking about the NWDA again.

9 Do you see the beginning of the
10 second paragraph?

11 And it references the fact that
12 the DEA was, in fact, aware that the -- some
13 of the distributors were adopting the NWDA
14 suspicious order monitoring system.

15 Beginning with where I've
16 highlighted, can you please read that into
17 the record?

18 A. Start with "can"?

19 Q. You can, like, ad lib to get to
20 can, but, yeah.

21 MR. EPPICH: Objection.

22 THE WITNESS: "The NWDA
23 suspicious order monitoring system,
24 SOM, which has been adopted by many
25 distributors throughout the United

1 States, can be an effective monitoring
2 and reporting system provided that the
3 firm's using it to recognize their
4 responsibility to actively monitor
5 sales to detect suspicious orders."

6 QUESTIONS BY MR. FARRELL:

7 Q. Is this consistent with the
8 guidance provided by the DEA to wholesale
9 distributors and manufacturers of
10 prescription opioids?

11 MR. EPPICH: Object to form.

12 Foundation.

13 THE WITNESS: Yes.

14 QUESTIONS BY MR. FARRELL:

15 Q. Now, at the very bottom, there
16 is a discussion from the director beginning
17 with the last paragraph on the bottom of the
18 page beginning "what is -- what is of
19 particular concern."

20 Can you please read that into
21 the record?

22 A. "What is of particular concern
23 to me is the statement that appears on the
24 report submitted by the McKesson Corporation
25 in Fort Worth, Texas. For example, 'With the

1 submission of this report, we are leaving to
2 the DEA the final determination of whether
3 they are suspicious or unusual.' This
4 position is unacceptable and clearly in
5 contravention to the requirements of 21 CFR
6 1301.74(b).

7 "A registrant whose own
8 personnel are in the best position to
9 determine what is excessive or unusual based
10 on knowledge of their customers and usual
11 purchasing practices may not abrogate its
12 responsibility to identify suspicious orders
13 and to determine whether to ship or refuse to
14 ship the controlled substance order.

15 "The registrant must also
16 report any suspicious orders as soon as
17 possible to the DEA. This has been conveyed
18 to the McKesson national management in San
19 Francisco, and they have agreed to remove the
20 statement from reports."

21 Q. So on behalf of the DEA, can
22 you validate that this is a true and accurate
23 summary of the conversation between the DEA
24 and McKesson?

25 MR. FINKELSTEIN: Scope.

1 MR. MAHADY: Object to form.

2 THE WITNESS: Yes.

3 QUESTIONS BY MR. FARRELL:

4 Q. Is this consistent with the
5 guidance that DEA provided not only to
6 McKesson but to every other wholesale
7 distributor and manufacturer of prescription
8 opioids?

9 MR. EPPICH: Object to form.
10 Foundation.

11 MR. MAHADY: Objection.

12 MR. FINKELSTEIN: Scope.

13 THE WITNESS: Yes.

14 QUESTIONS BY MR. FARRELL:

15 Q. Now, follow up real quick. You
16 see here where it says that "a registrant may
17 not abrogate its responsibility"? I have a
18 follow-up question to that.

19 Is a registrant permitted to
20 delegate this -- its obligations to design
21 and operate a system to maintain effective
22 control against diversion to a third party
23 and avoid being held responsible by the DEA?

24 MR. EPPICH: Object to form.

25 THE WITNESS: Could you please

1 repeat that?

2 QUESTIONS BY MR. FARRELL:

3 Q. Is a registrant allowed to
4 delegate its obligations under 1301.74(b) to
5 another party to perform and escape liability
6 from the DEA for failure to comply?

7 MR. EPPICH: Objection to form.

8 MR. MAHADY: Foundation.

9 MR. FINKELSTEIN: Scope.

10 THE WITNESS: No.

11 QUESTIONS BY MR. FARRELL:

12 Q. So if a registrant that has an
13 obligation under the CSA delegates the
14 responsibilities to, say, UPS and/or Federal
15 Express and a violation occurs, is the
16 registrant ultimately still responsible for
17 those violations?

18 MR. EPPICH: Objection to form.

19 Calls for a legal conclusion. Scope.

20 MR. FINKELSTEIN: Incomplete
21 hypothetical.

22 THE WITNESS: I'm sorry, can
23 you please repeat it?

24 QUESTIONS BY MR. FARRELL:

25 Q. If Actavis delegates to UPS

1 their obligations to maintain effective
2 control, and the DEA determines in their best
3 judgment and upon investigation that a
4 violation has occurred, does the DEA take the
5 position that Actavis is still ultimately
6 responsible for the violation?

7 MS. MATIC: Objection to form.

8 MR. EPPICH: Object to form.

9 Calls for a legal conclusion. Scope.

10 THE WITNESS: Yes.

11 QUESTIONS BY MR. FARRELL:

12 Q. Would the DEA in fact
13 investigate and, if they found probable
14 cause, prosecute both UPS and Actavis under
15 that hypothetical?

16 MS. MAINIGI: Objection.

17 Scope. Calls for a legal conclusion.

18 Hypothetical. Form.

19 MR. FINKELSTEIN: Let me
20 object. Scope.

21 THE WITNESS: I would agree we
22 would investigate. I don't -- I don't
23 know where the investigation would go,
24 but we would investigate it.

25

1 QUESTIONS BY MR. FARRELL:

2 Q. And if you found that UPS
3 violated the Controlled Substances Act, would
4 you prosecute both UPS and Actavis?

5 A. It, again, depends --

6 MS. MAINIGI: Same objections.

7 MR. FINKELSTEIN: Scope.

8 THE WITNESS: Depends on what
9 the evidence shows, but we would
10 investigate it, both parties.

11 QUESTIONS BY MR. FARRELL:

12 Q. That's fair. It's tough to
13 give a hypothetical with this scenario, so
14 let me see if I can be more direct.

15 If Cardinal Health delegates
16 its obligations under 1301.74(b) to CVS to
17 police themselves, is that -- does the DEA
18 consider that in compliance with federal law?

19 MS. MAINIGI: Objection.

20 Scope. Incomplete hypothetical.

21 Foundation. Form.

22 MR. FINKELSTEIN: Join as to
23 incomplete hypothetical.

24 THE WITNESS: No.

25 (Prevoznik Plaintiff's Exhibit

1 P21 marked for identification.)

2 QUESTIONS BY MR. FARRELL:

3 Q. I'm going to mark next what's
4 going to be P21 and hand it to you. And I'll
5 have you look at the bottom right-hand
6 corner. You'll note that there's a Bates
7 stamp US-DEA-00025302.

8 Do you recognize this document?

9 A. Yes.

10 Q. What is it?

11 A. It's a Federal Register
12 announcing that there's going to be a meeting
13 for the task force on suspicious orders
14 December 16th and 17th of 1997.

15 Q. Does the DEA publish in the
16 Federal Register notices for the entire world
17 that can read English to read?

18 MS. MAINIGI: Objection.

19 THE WITNESS: Yes.

20 QUESTIONS BY MR. FARRELL:

21 Q. You'll note that this in
22 particular Federal Register action has been
23 labeled "Notice of Establishment of Task
24 Force on Suspicious Orders."

25 Do you see that?

1 A. Is this a different...

2 Q. It should be the same one. If
3 you look at what I highlighted there, it's
4 only one page.

5 A. It's only one page?

6 Q. Yeah. You see where my finger
7 is right here?

8 A. That one. Sorry. Yeah.
9 Sorry, I'm good.

10 Q. All right. Now, if you look,
11 I'm going to -- I'm going to give you a
12 chance to take a read, but I'm going to
13 summarize it for you.

14 Is this the DEA's publication
15 and notice to the public that it was forming
16 a task force on suspicious orders pursuant to
17 the Comprehensive Methamphetamine Control Act
18 of 1996?

19 MR. FINKELSTEIN: Take your
20 time to read it if you need to.

21 MS. MAINIGI: Objection.

22 THE WITNESS: Yes.

23 QUESTIONS BY MR. FARRELL:

24 Q. All right. Now, when you look
25 at the public notice, it states that "the DEA

1 is establishing a task force on suspicious
2 orders for the purpose of developing
3 proposals to define suspicious orders of
4 listed chemicals."

5 Do you see that?

6 A. Yes.

7 Q. As we discussed at length
8 before, prescription opioids are not
9 necessarily listed chemicals, are they?

10 MR. EPPICH: Object to form.
11 Foundation. Calls for speculation.

12 THE WITNESS: Yes.

13 QUESTIONS BY MR. FARRELL:

14 Q. Well, let's be a little more
15 direct.

16 The DEA makes proposals and
17 provides input on what should be a listed
18 chemical and what should be a controlled
19 substance, agreed?

20 A. Agreed.

21 Q. And the listed chemicals that
22 they're referencing in this public notice for
23 this task force relate to the Methamphetamine
24 Act and ephedrine and pseudoephedrine used to
25 make methamphetamine --

1 MR. EPPICH: Object to the
2 form.

3 QUESTIONS BY MR. FARRELL:

4 Q. Agreed?

5 MR. EPPICH: Objection. Form.

6 THE WITNESS: Yes.

7 QUESTIONS BY MR. FARRELL:

8 Q. And as we discussed previously,
9 suspicious orders of listed chemicals used to
10 make methamphetamine are defined as orders
11 that are extraordinary in size, agreed?

12 MR. FINKELSTEIN: Objection to
13 form. Calls for speculation.

14 THE WITNESS: Agreed.

15 QUESTIONS BY MR. FARRELL:

16 Q. And there's a different
17 standard and a different regulation that
18 govern controlled substances or suspicious
19 orders of controlled substances, agreed?

20 MR. EPPICH: Objection to form.

21 THE WITNESS: Agreed.

22 QUESTIONS BY MR. FARRELL:

23 Q. Now, when you look at this
24 notice, it says, "The proposals establish
25 guidelines that will adequately define

1 suspicious orders of listed chemicals."

2 Do you see that?

3 A. Yes.

4 Q. Does the DEA believe this task
5 force was assigned the project of defining
6 suspicious orders of controlled substances
7 that don't contain listed chemicals?

8 MR. EPPICH: Object to form.

9 Calls for speculation. Foundation.

10 THE WITNESS: No.

11 QUESTIONS BY MR. FARRELL:

12 Q. So the DEA not only was on this
13 task force, it was assigned the obligation by
14 Congress to form this task force. So I'm not
15 asking you to speculate. I'm asking the DEA
16 itself.

17 When you promulgated this
18 report to the Attorney General, were you
19 intending to provide any guidance to the
20 wholesale distributors and manufacturers of
21 prescription opioids that it should be using
22 the standards therein to measure whether or
23 not a suspicious order of controlled
24 substances falls under the federal
25 regulations?

1 MR. EPPICH: Object to form.

2 MR. O'CONNOR: Objection.

3 Foundation.

4 MS. MAINIGI: Also scope.

5 THE WITNESS: No.

6 QUESTIONS BY MR. FARRELL:

7 Q. Now, if you look at the bottom
8 right-hand corner, you'll see who the DEA was
9 tasked to add to this task force.

10 Did the DEA, in fact, add to
11 this task force a member from the National
12 Association of Boards of Pharmacy?

13 A. Yes.

14 Q. And members from the Chemical
15 Manufacturers Association?

16 A. Yes.

17 Q. And members from the National
18 Association of Chemical Distributors?

19 A. Yes.

20 Q. And a member from the
21 Nonprescription Drug Manufacturers
22 Association?

23 A. Yes.

24 Q. And, in fact, four members from
25 the wholesale and retail pharmaceutical

1 marketing associations?

2 A. Yes.

3 (Prevoznik Plaintiff Exhibits
4 P22, P23, P24 and P25 marked for
5 identification.)

6 QUESTIONS BY MR. FARRELL:

7 Q. All right. I've got three
8 documents I'm going to show you now, and
9 they're going to be marked separately P22,
10 P23 and P24. Oops, and P25. There's four
11 documents in total.

12 And I'll give you a second to
13 review it while we pass it around the table.

14 MR. FINKELSTEIN: I have three
15 documents. Because mine are not
16 marked, perhaps you can just tell me
17 which is which in terms of exhibit
18 number?

19 MR. FARRELL: Yeah, the
20 first -- they should be in
21 chronological order. So it should go
22 AmerisourceBergen first. The top
23 right is August 16, 2005, Bates stamp
24 US-DEA-00000147.

25 The next one should be --

1 MR. FINKELSTEIN: You didn't
2 give me 147.

3 Okay. 147 is 22, correct?

4 MR. FARRELL: Yes.

5 MR. FINKELSTEIN: Okay.

6 MR. FARRELL: The next one is
7 Cardinal Health, I believe, and it
8 bears Bates stamp US-DEA, a bunch of
9 zeros, and then 352.

10 MR. FINKELSTEIN: Okay.

11 MR. FARRELL: Then the next
12 one, I believe, should be December 6,
13 2005, and in the bottom right-hand
14 corner is US-DEA-00000369.

15 And then the final one is dated
16 January 23, 2006, in the bottom
17 right-hand corner is US-DEA-00000371.

18 MR. FINKELSTEIN: Okay.

19 QUESTIONS BY MR. FARRELL:

20 Q. Let me know when you're ready
21 to proceed.

22 Do you want to take a few
23 minutes to read these?

24 A. Yes, please.

25 Q. Do you want to take a quick

1 break while we do so?

2 MS. SINGER: Let's keep going.

3 MR. EPPICH: Do we typically go
4 off the record to review documents?

5 SPECIAL MASTER COHEN: No.

6 MR. FARRELL: I didn't say
7 that. I said -- I asked him if he
8 wanted to take a break, and he said
9 no.

10 QUESTIONS BY MR. FARRELL:

11 Q. I don't know if this will save
12 you some time. I'm not intending on quizzing
13 you on the contents of these, other than
14 establishing what they are and the foundation
15 for what the DEA was doing.

16 A. Okay.

17 Q. I'm going to ask you first: Do
18 you recognize these documents?

19 A. Yes.

20 Q. Okay. What are they
21 collectively?

22 A. Collectively they represent
23 what happened with meetings with the
24 respective registrants, AmerisourceBergen,
25 Cardinal, McKesson and -- I see McKesson

1 twice.

2 Q. Okay. So in general, are these
3 the documents the DEA created to internally
4 memorialize the initial meetings in and
5 around 2005 that the jury has heard about
6 related to what's called the distributor
7 initiative?

8 A. Yes.

9 Q. Now, these documents weren't
10 provided to the registrants, were they?

11 A. These reports?

12 Q. Correct.

13 A. Correct.

14 Q. But these documents were
15 created -- let me back up.

16 Do you have knowledge of
17 whether these documents were made at or near
18 the time of the meetings?

19 MR. EPPICH: Objection.

20 Foundation.

21 THE WITNESS: Well, from the
22 date stamp, it's around those dates.

23 QUESTIONS BY MR. FARRELL:

24 Q. Is this reflective of the
25 practice of the DEA, with regard to the

1 distributor initiative, to document what
2 happened during the meetings with
3 registrants?

4 A. Yes.

5 Q. Now, the DEA has conducted
6 hundreds of these meetings, correct?

7 MS. MAINIGI: Objection.

8 THE WITNESS: Correct.

9 QUESTIONS BY MR. FARRELL:

10 Q. So rather than go through all
11 of them, if one of these memorandums contains
12 a Bates stamp of US DEA and is produced by
13 the Department of Justice in this litigation,
14 is it the DEA's position that the photocopy
15 being submitted is a true and accurate copy
16 of the original?

17 MR. MAHADY: Objection.

18 Foundation.

19 THE WITNESS: Yes.

20 QUESTIONS BY MR. FARRELL:

21 Q. Does the DEA acknowledge that
22 all of those such documents bearing the
23 US DEA Bates stamp are, in fact, in the
24 possession, custody and control of the DEA
25 and document the discussions and contents of

1 each distributor initiative meeting?

2 A. Yes.

3 Q. So in particular what I'd ask
4 you to do is to go to the very -- is to go to
5 the first one, which is AmerisourceBergen's,
6 and you'll see that this is the summary of
7 the meeting on August 10, 2005.

8 Do you see that?

9 A. Yes.

10 Q. And it goes through and it
11 describes all of the things that were
12 discussed in the documents that were provided
13 during the meeting.

14 Do you see that?

15 A. Yes.

16 Q. Now, I'll represent to you that
17 I'm not going to produce all of the thousands
18 of pages as an exhibit, but I'll represent to
19 you that there are, in fact, exhibits that go
20 with this that the DEA produced in this
21 litigation.

22 Agreed?

23 MR. MAHADY: Objection. Form.

24 Objection to foundation.

25 THE WITNESS: Yes.

1 QUESTIONS BY MR. FARRELL:

2 Q. Now, one of the things I'd like
3 to direct your attention to is that many of
4 the distributors have made the statement that
5 this presentation was only related to
6 Internet pharmacies. And in fact, I believe
7 they asked you that question during the time
8 that they deposed you for the previous two
9 days.

10 What I'd ask you to do is I'd
11 ask you to turn to page 7 of the PowerPoint
12 presentation with AmerisourceBergen.

13 And you see where it says,
14 "Report suspicious orders to DEA when
15 discovered"?

16 Do you see that?

17 A. Yes.

18 Q. So this is the PowerPoint slide
19 by the DEA with AmerisourceBergen as early as
20 2005.

21 Agreed?

22 A. Agreed.

23 Q. And if you look at the next
24 slide, it states, "Reporting a suspicious
25 order to the DEA does not relieve the

1 distributor of the responsibility to maintain
2 effective controls against diversion."

3 Did I read that accurately?

4 A. Yes.

5 Q. Okay. Why did the DEA put the
6 word "not" in all caps?

7 A. To emphasize that they had to
8 provide the suspicious order, not just -- not
9 just after-sales reports.

10 Q. The next slide, it says, "The
11 DEA cannot tell a distributor if an order is
12 legitimate or not" and that "the distributor
13 must determine which orders are suspicious
14 and make a sales decision."

15 Is this similar to all of the
16 other slide shows the DEA provided to the
17 distributors back in the 2000 -- 2005, 2006
18 time frame?

19 MR. MAHADY: Objection to form.

20 Objection to foundation.

21 THE WITNESS: Yes.

22 QUESTIONS BY MR. FARRELL:

23 Q. In other words, this PowerPoint
24 presentation, was it a stock PowerPoint
25 presentation that was shown to Cardinal

1 Health?

2 A. Yes.

3 Q. Was it shown to McKesson?

4 A. Yes.

5 Q. Was it shown to CVS?

6 MS. FUMERTON: Objection.

7 Form. Lack of foundation.

8 MR. FARRELL: That actually
9 might be right.

10 QUESTIONS BY MR. FARRELL:

11 Q. Was it -- to all of the
12 distributors that the DEA met with in 2005
13 and 2006, is this the stock PowerPoint
14 presentation that was used?

15 A. Yes.

16 MS. FUMERTON: Objection.

17 QUESTIONS BY MR. FARRELL:

18 Q. So I'm also going to have you
19 flip to page 12.

20 In the summary slides, the very
21 last bullet point, can you read what that
22 says?

23 A. "Not limited to Internet
24 pharmacies."

25 Q. What does that mean?

1 MR. EPPICH: Object to form.

2 Foundation.

3 QUESTIONS BY MR. FARRELL:

4 Q. Go ahead.

5 A. It's not just the -- what the
6 Internet pharmacies was, but it would be any
7 pharmacy, retail.

8 Q. The very next slide, it says,
9 "A pattern of drugs being distributed to
10 pharmacies who are diverting controlled
11 substances demonstrates the lack of effective
12 controls against diversion by the
13 distributor."

14 This PowerPoint presentation in
15 the distributor initiative meeting, it was
16 not just limited to rogue Internet
17 pharmacies, was it?

18 MR. EPPICH: Object to form.

19 Foundation. Calls for speculation.

20 THE WITNESS: No. The emphasis
21 was regarding the Internet, but it was
22 for the totality of their
23 responsibilities as a registrant.

24 QUESTIONS BY MR. FARRELL:

25 Q. But as consistent with the very

1 next sentence, did the DEA make it clear to
2 those distributors that it met with in 2005
3 and 2006 that if they didn't comply with
4 federal law regarding the detection, the
5 reporting and the halting of suspicious
6 orders, that the DEA may revoke their
7 registration?

8 MR. MAHADY: Objection to form.

9 THE WITNESS: Yes.

10 QUESTIONS BY MR. FARRELL:

11 Q. Cardinal Health is the next
12 plaintiff's exhibit, Bates-stamped
13 US-DEA-352. And just to make sure that
14 there's no hanky-panky, you'll see that the
15 PowerPoint slide is attached to this document
16 as well and is consistent with all the other
17 PowerPoint slides provided to the -- or all
18 the other distributor initiative meetings.

19 Would you agree with that?

20 MS. FUMERTON: Objection.

21 Form.

22 THE WITNESS: Yes.

23 MS. FUMERTON: Lack of
24 foundation.
25

1 QUESTIONS BY MR. FARRELL:

2 Q. Now, the next one is McKesson,
3 and we're going to take a real quick stop to
4 take a look at this one.

5 This is dated -- the first one
6 is December 6, 2005, and it appears to be a
7 conference call with Mr. John Gilbert.

8 Do you see that?

9 A. Yes.

10 Q. And Mr. Mapes and Kyle Wright
11 of the DEA.

12 Who are Mr. Mapes and
13 Mr. Wright of the DEA?

14 A. Mr. Mapes was the section chief
15 of our E-Commerce section, and Kyle Wright at
16 this time was a staff coordinator in
17 Mr. Mapes' section.

18 Q. So the next plaintiff's exhibit
19 has the Bates stamp at the bottom corner of
20 US-DEA-00000371, and you'll see that it's
21 dated January 23, 2006, but it's referencing
22 a January 3, 2006 meeting.

23 Do you see that?

24 A. Yes.

25 Q. And in it you can see where it

1 looks like it contains -- this is the
2 memorandum of the meeting between McKesson
3 and the DEA as a result of the distributor
4 initiative. Agreed?

5 MR. EPPICH: Object to form and
6 foundation.

7 THE WITNESS: Yes.

8 QUESTIONS BY MR. FARRELL:

9 Q. Now, what I'm going to ask you
10 to do is I'm going to ask you to go to the
11 end of page 2. And at the bottom, starting
12 with the word "after," the very last
13 paragraph, I'd ask you to read that into the
14 record.

15 A. "After the conclusion of this
16 meeting, it was learned from Gary Hilliard of
17 McKesson Corp that one of the reasons they
18 were not able to realize the full volume of
19 hydrocodone product going out to the Florida
20 pharmacies was that their reports only
21 included the name brand hydrocodone products
22 distributed and was leaving out the generic
23 products."

24 Q. The next sentence.

25 A. "It was only after realizing

1 that the generic were not being reported was
2 McKesson Corp then able to see the large
3 quantities that DEA was bringing to
4 McKesson's attention."

5 Q. So I don't know how to say this
6 any other way, but in 2006 when the DEA met
7 with McKesson with its distributor initiative
8 program, was it discovered that McKesson was
9 only tracking the brand name prescription
10 opiates?

11 MR. EPPICH: Object to form.
12 Foundation. Calls for speculation.
13 Scope.

14 THE WITNESS: Could you please
15 repeat it?

16 QUESTIONS BY MR. FARRELL:

17 Q. This document, following the
18 distributor initiative meeting between the
19 DEA and McKesson, appears to present the fact
20 that the DEA discovered McKesson was only
21 tracking brand name prescription opiates.

22 A. Correct.

23 MR. EPPICH: Object to the
24 form. Foundation. Calls for
25 speculation.

1 THE WITNESS: Correct.

2 QUESTIONS BY MR. FARRELL:

3 Q. If, in fact, McKesson was only
4 tracking brand name prescription opiates and
5 leaving out the generic products, is that a
6 violation of federal law?

7 MR. EPPICH: Object to form.
8 Foundation. Calls for speculation.
9 Calls for a legal conclusion.

10 THE WITNESS: Yes.

11 QUESTIONS BY MR. FARRELL:

12 Q. Sitting here today as the
13 custodian of ARCOS and the institutional
14 knowledge of the Drug Enforcement
15 Administration, if this is true, how many
16 generic prescription orders do you estimate
17 that McKesson missed prior to 2005?

18 MR. EPPICH: Object to the
19 form. Calls for speculation. Calls
20 for a legal conclusion, and I believe
21 it would be outside the Touhy
22 authorization.

23 MS. MAINIGI: Join.

24 MR. FINKELSTEIN: Scope. Calls
25 for speculation.

1 You can answer in your personal
2 capacity, but not on behalf of the
3 DEA.

4 THE WITNESS: I have no idea.

5 QUESTIONS BY MR. FARRELL:

6 Q. A lot?

7 MR. EPPICH: Same objections.

8 MR. FINKELSTEIN: Same
9 objection.

10 THE WITNESS: Yes.

11 QUESTIONS BY MR. FARRELL:

12 Q. All right. On a scale of 0 of
13 10 of screw-ups, how big of a screw-up is
14 this?

15 MR. EPPICH: Object to form.
16 Argumentative.

17 MR. FINKELSTEIN: Same
18 objection.

19 You can answer in your personal
20 capacity, but not on behalf of the
21 DEA.

22 THE WITNESS: In my personal
23 capacity, a big one, a really big one.

24 QUESTIONS BY MR. FARRELL:

25 Q. Epic?

1 A. Yes.

2 MR. EPPICH: Same objections.

3 (Prevoznik Plaintiff's Exhibit
4 P26 marked for identification.)

5 QUESTIONS BY MR. FARRELL:

6 Q. We're now going to jump ahead a
7 little bit. I'm going to show you what's
8 next marked as Plaintiff's 26.

9 This is a series of letters
10 that the DEA, institutionally and with
11 perfect recollection, will recall that --
12 between the lawyers for Cardinal Health and
13 the DEA, the first time they got in trouble
14 for breaking the law in 2008.

15 MS. MAINIGI: Objection.

16 Scope. Foundation. Form.

17 QUESTIONS BY MR. FARRELL:

18 Q. Now, without having to go
19 through all of the nuances, what I'm going to
20 ask you to do is I'm going to make a
21 reference now. At the bottom right-hand
22 corner is Bates stamp CAH_MDL2804_01376799.

23 Do you see that? 799 are the
24 last three numbers.

25 A. Yes, I have it.

1 Q. Now, in it, in this letter,
2 Larry -- to Larry Cote from Cardinal Health's
3 lawyers, it seems to indicate that controlled
4 substances that are sold by Cardinal Health
5 to CVS, Walgreens, Kroger, Kmart and Winn
6 Dixie, which are large, national or regional
7 chains, pose no threat of diversion due to
8 their sophisticated anti-diversion systems
9 and historical record of compliance.

10 Do you see that?

11 MS. MAINIGI: Objection. Form.

12 Scope. Foundation.

13 THE WITNESS: Yes.

14 QUESTIONS BY MR. FARRELL:

15 Q. Did I read that accurately?

16 A. Yes.

17 MS. MAINIGI: Objection.

18 THE WITNESS: Yes.

19 QUESTIONS BY MR. FARRELL:

20 Q. Aside from me reading that
21 accurately, is it true that large, national,
22 regional chains of pharmacies pose no threat
23 of diversion of prescription opioids?

24 MS. MAINIGI: Objection. Form.

25 Scope. Foundation.

1 THE WITNESS: It's not true.

2 QUESTIONS BY MR. FARRELL:

3 Q. In fact, the DEA has
4 investigated and prosecuted many of the large
5 national or regional chains, including CVS
6 and Walgreens?

7 MS. MAINIGI: Objection. Form.
8 Scope. Foundation.

9 MR. FINKELSTEIN: Objection.
10 Do not testify based on current
11 or ongoing investigations. You can
12 answer based on historical
13 investigations or prosecutions.

14 THE WITNESS: Yes.

15 QUESTIONS BY MR. FARRELL:

16 Q. If a wholesale distributor
17 decides not to monitor a chain store
18 pharmacy, is that a per se violation of
19 federal law?

20 MR. EPPICH: Object to form.
21 Calls for a legal conclusion.

22 MS. MAINIGI: Scope.

23 QUESTIONS BY MR. FARRELL:

24 Q. According to the DEA.

25 MR. EPPICH: Same objection.

1 THE WITNESS: Could you please
2 repeat it?

3 QUESTIONS BY MR. FARRELL:

4 Q. Does the DEA consider -- if a
5 wholesale distributor came to the DEA and
6 said, "I've got a new customer and it's CVS,
7 which is a national chain store, and because
8 they have such swell security, I don't want
9 to monitor them for suspicious orders. Is
10 that okay?"

11 MR. EPPICH: Object to the
12 form.

13 QUESTIONS BY MR. FARRELL:

14 Q. What would the DEA say?

15 MR. EPPICH: Object to form and
16 incomplete hypothetical. Calls for a
17 legal conclusion. Foundation.

18 MS. MAINIGI: Scope.

19 THE WITNESS: They can't do
20 that.

21 QUESTIONS BY MR. FARRELL:

22 Q. And what if I said, "I'm going
23 to do it anyway"?

24 MR. EPPICH: Same objection.

25 MS. MAINIGI: Same objection.

1 THE WITNESS: It's a decision
2 that they're making, and we're going
3 to investigate it and we're going to
4 do what we -- what we need to do to
5 protect the public.

6 QUESTIONS BY MR. FARRELL:

7 Q. And what would you need to do
8 to protect the public?

9 MR. FINKELSTEIN: Hang on.
10 Incomplete hypothetical.

11 MS. MAINIGI: Objection. Form.

12 THE WITNESS: We would
13 investigate to see where the orders
14 went and how much went and who was --
15 what they were filling and who had
16 knowledge of what. What we normally
17 do with our investigations.

18 QUESTIONS BY MR. FARRELL:

19 Q. All right. Would the DEA
20 provide guidance to such a wholesale
21 distributor, that regardless of whether its
22 customer is a national chain pharmacy, the
23 distributor still must comply with
24 1301.74 (b)?

25 A. Yes.

1 MR. EPPICH: Objection to form.

2 QUESTIONS BY MR. FARRELL:

3 Q. What if I said to you, "Well,
4 how about this: How about if I only start
5 monitoring them after they reach a cap of
6 20,000 pills in a month?" Would you deem
7 that to be compliant with federal law?

8 MR. EPPICH: Object to the
9 form. Incomplete hypothetical. Calls
10 for a legal conclusion.

11 MR. FINKELSTEIN: Incomplete
12 hypothetical.

13 THE WITNESS: No.

14 QUESTIONS BY MR. FARRELL:

15 Q. Now, in these correspondence
16 Cardinal Health's lawyers represent that
17 they're going to retain -- let me see if I
18 can find the right word and avoid an
19 objection.

20 You'll see here a consulting
21 firm named Cegedim Dendrite and that they're
22 going to provide the reports on controlled
23 substance orders to the DEA.

24 Do you see that?

25 A. What page are we on?

1 Well, I would prefer to know
2 what page we're on.

3 Q. Okay. This is the -- the last
4 three digits are 803. And it's the first
5 full paragraph.

6 A. Okay.

7 Q. There's another reference in
8 here to Cegedim Dendrite, and I'll represent
9 to you that the correspondence indicates that
10 Cardinal Health was telling the DEA, "Please
11 don't revoke our license or suspend our
12 license or fine us. We're going to hire this
13 outside consultant, and we're going to share
14 the report with you." I'm going to make that
15 representation.

16 Has the DEA, in fact, ever seen
17 that report?

18 MR. FINKELSTEIN: Scope.

19 THE WITNESS: I don't know. I
20 don't know.

21 (Prevoznik Plaintiff's Exhibit
22 P27 marked for identification.)

23 QUESTIONS BY MR. FARRELL:

24 Q. I'm going to have marked as
25 Plaintiff's Exhibit 27 and circulate a

1 document that bears the Bates stamp in the
2 bottom right-hand corner
3 CAH_MDL2804_03309960.

4 Have you -- has the DEA, in its
5 vast institutional knowledge, ever seen this
6 document before?

7 MS. MAINIGI: Objection.

8 Scope. Objection. Form.

9 MR. FINKELSTEIN: Scope.

10 MS. MAINIGI: Mr. Finkelstein,
11 I'm assuming when you make a scope
12 objection that means you're
13 instructing him to answer in his
14 individual capacity?

15 MR. FINKELSTEIN: When I make a
16 scope objection and when I have made
17 such objections in the past, it should
18 be understood that you can answer
19 based on your personal knowledge in
20 your individual capacity, but your
21 answers do not bind the DEA.

22 Do you understand that?

23 THE WITNESS: Yes.

24 MR. FARRELL: So we're going
25 to -- David, we're going to need you.

1 I did not understand that when
2 you made an objection for scope that
3 we needed to preserve the right to be
4 able to -- that I was waiving my right
5 to have that objection ruled or
6 overruled.

7 So I disagree that every time
8 the Department of Justice makes an
9 objection on scope that transforms the
10 witness from a Rule 30(b)(6) designee
11 into a witness testifying in his own
12 capacity, because we did not notice
13 the deposition of Mr. Prevoznik in his
14 individual capacity. We noticed
15 him -- we noticed the DEA put a
16 witness up in its capacity.

17 That being said, perfectly
18 willing to allow the record to be
19 preserved with appropriate objections
20 to be addressed with Judge Polster,
21 but I believe Judge Polster has the
22 ultimate say in whether or not our
23 questions are admissible and whether
24 or not they fall inside or outside of
25 the scope of the 30(b)(6) notice.

1 MR. FINKELSTEIN: So my
2 response would be if Judge Polster
3 disagrees with my objections, then
4 Judge Polster will make appropriate
5 rulings.

6 If you disagree with my
7 objections, my proposal would be to
8 review the objections I've made at a
9 break, and we can take them up with
10 the Special Master as necessary.

11 MR. FARRELL: All right. We've
12 been going for an hour, so maybe this
13 is the right time to take a quick
14 break.

15 VIDEOGRAPHER: We're going off
16 the record. The time is 9:12.

17 (Off the record at 9:12 a.m.)

18 VIDEOGRAPHER: We are back on
19 record. Beginning of Media File 2.
20 The time is 9:27.

21 SPECIAL MASTER COHEN: So with
22 regard to the issue that came up just
23 before we went off the record, I think
24 to make the record clear as we go
25 forward, it would help if, rather than

1 merely saying "scope," when the DEA
2 has an objection that the answer is
3 outside the scope of Touhy authority,
4 that you just say that, "outside the
5 scope of Touhy authority."

6 With regard to the question of
7 whether it is outside the scope of
8 Touhy authority, I think the Court
9 does retain jurisdiction to make that
10 determination in the final event, as
11 with any objection.

12 And I will add that my own
13 understanding is that it's unclear
14 exactly whether a witness is allowed
15 to answer questions even though he
16 doesn't have authority under Touhy. I
17 think that's actually an open question
18 legally. But in any event, we don't
19 have to address that question now.

20 So when you are directed,
21 Mr. Prevoznik, to answer only within
22 the scope of your personal knowledge
23 and not as a -- with DEA authority,
24 that's what we'll assume you're doing.

25 Okay?

1 THE WITNESS: Yes.

2 SPECIAL MASTER COHEN:

3 Everybody understand that? Any
4 questions?

5 MS. SINGER: Nope.

6 MR. FINKELSTEIN: I'm happy to
7 expand on my objections, and I'm happy
8 to explain them as necessary.

9 SPECIAL MASTER COHEN: No, we
10 can do it in shorthand. I just want
11 to make sure we understand things,
12 that we're all on the same page going
13 forward.

14 Okay?

15 MS. MAINIGI: There will be no
16 ruling on those objections?

17 SPECIAL MASTER COHEN: Correct.

18 EXAMINATION

19 QUESTIONS BY MS. SINGER:

20 Q. All right. Good morning,
21 Mr. Prevoznik. Mr. Farrell was nice enough
22 to cover some of the things I was planning
23 to, so we're going to shorthand our way
24 through some of the opening topics.

25 Now, remind the jury, how long

1 have you been with the DEA?

2 A. Over 28 years.

3 Q. Okay. And during the course of
4 your 20 years with the DEA, I imagine that
5 the drugs being diverted may have changed; is
6 that correct?

7 A. Yeah, that's trend shifts.

8 Q. And the means of diverting
9 those drugs may have changed over time as
10 well?

11 A. Yes.

12 Q. And the focus of DEA's
13 enforcement activities may have changed also
14 during that time; is that correct?

15 A. Correct.

16 Q. But the DEA's rules and
17 expectations with respect to the Controlled
18 Substances Act and CFR 1301.74, those have
19 remained the same, have they not?

20 MS. MAINIGI: Objection.

21 THE WITNESS: Yes.

22 (Prevoznik Plaintiff's Exhibit
23 P29 marked for identification.)

24 QUESTIONS BY MS. SINGER:

25 Q. All right. So we're going to

1 go quickly through the guidelines you talked
2 about. We're going to start with a
3 shorthand. And the first refers to what we
4 marked as Exhibit 18, is the backup for that.

5 So here you'll see the NWDA
6 suspicious order monitoring system, which we
7 were shown as Exhibit 18.

8 Is that familiar to you?

9 A. Yes.

10 Q. Okay. So in 1984 --

11 MR. FINKELSTEIN: I'm sorry,
12 Counsel, is this 18 or 29?

13 MS. SINGER: I think it's 18.

14 MR. FINKELSTEIN: It's marked
15 as 29.

16 MS. SINGER: I'm sorry. Oh,
17 I'm sorry, the new exhibit is 29. The
18 backup of the whole policy is
19 Exhibit 18.

20 MR. FINKELSTEIN: Okay.

21 QUESTIONS BY MS. SINGER:

22 Q. Okay. And just directing your
23 attention very quickly to 2, sub 2, on your
24 monitor -- I'm sorry, 9 on your monitor,
25 single suspicious orders, is it correct that

1 this suspicious order monitoring system
2 publication from 1984 established that
3 "single orders of unusual size or deviation
4 must be reported immediately, the submission
5 of monthly printout of after-the-fact sales
6 will not relieve a registrant from the
7 responsibility of reporting these single
8 excessive or suspicious orders. DEA has
9 interpreted orders to mean prior to
10 shipment"?

11 Does that accurately reflect
12 the policy of the DEA?

13 A. Yes.

14 Q. And that's as of 1984, correct?

15 A. Correct.

16 Q. All right. Turning next to
17 1987 is our next marker in the timeline.

18 And I'm sorry, just to be
19 perfectly clear, from 1971 to the present,
20 when the Controlled Substances Act was first
21 enacted in '71, has it been the DEA's
22 position that ILRs are not suspicious order
23 reports?

24 MS. MAINIGI: Objection.

25 THE WITNESS: Yes.

1 QUESTIONS BY MS. SINGER:

2 Q. And do ILRs relieve a
3 registrant -- does submitting ILRs relieve a
4 registrant of the obligation to report
5 suspicious orders?

6 MS. MAINIGI: Objection.

7 THE WITNESS: No.

8 QUESTIONS BY MS. SINGER:

9 Q. All right. The next marker,
10 1987, is that seminar report which was
11 Prevoznik 17, and that established any system
12 must be capable of both detecting individual
13 orders or -- which are suspicious orders,
14 which become suspicious over time due to
15 frequency, quantity or pattern.

16 Is that consistent with the
17 DEA's policy?

18 A. Yes.

19 Q. And the DEA pointed out that
20 the company is still responsible under their
21 registrations for acting in the public
22 interest, reporting the order does not in any
23 way relieve the firm from the responsibility
24 for the shipment.

25 Does that also reflect the

1 DEA's policy consistently over time?

2 MS. MAINIGI: Objection.

3 MR. O'CONNOR: Objection.

4 THE WITNESS: Yes.

5 (Prevoznik Plaintiff Exhibit

6 P33 marked for identification.)

7 QUESTIONS BY MS. SINGER:

8 Q. Okay. I want to turn next to a
9 new document, and that's the DEA's Diversion
10 Investigators Manual.

11 Can we mark this as -- what are
12 we up to?

13 MR. FINKELSTEIN: 30.

14 MS. SINGER: Thank you.

15 (Prevoznik Exhibit 33 marked
16 for identification.)

17 MR. FINKELSTEIN: Is there no
18 28? Have we skipped 28? I don't
19 mind. I just want to make sure I have
20 everything.

21 QUESTIONS BY MS. SINGER:

22 Q. Mr. Prevoznik, showing you
23 Exhibit 33. Do you recognize this document?

24 A. Yes.

25 Q. And what do you recognize that

1 document to be?

2 MS. MAINIGI: Excuse me,
3 Counsel. May I have a copy?

4 QUESTIONS BY MS. SINGER:

5 Q. What do you recognize that
6 document to be?

7 A. DEA's Diversion Investigators
8 Manual.

9 Q. And what is that -- what is the
10 Diversion Investigators Manual used for?

11 MR. EPPICH: Objection. Form.

12 THE WITNESS: It's used to
13 guide us, diversion investigators, on
14 how to do our jobs.

15 QUESTIONS BY MS. SINGER:

16 Q. Okay. And so that is internal
17 guidance provided by the DEA to its diversion
18 investigators, correct?

19 A. Correct.

20 Q. Okay. And do you know the year
21 of that version of the manual?

22 And again, it's not a quiz.

23 Does it seem like 1990, which was the
24 information provided to us, is accurate?

25 MR. EPPICH: Objection. Calls

1 for speculation.

2 THE WITNESS: Yes.

3 QUESTIONS BY MS. SINGER:

4 Q. Okay. And is the Diversion
5 Investigators Manual updated periodically by
6 the DEA?

7 A. Yes.

8 Q. And do you know whether at
9 least parts of the Diversion Investigators
10 Manual have been provided to distributors
11 through public record requests?

12 MS. MAINIGI: Objection.

13 Scope. Or outside Touhy
14 authorization.

15 THE WITNESS: I don't know.

16 QUESTIONS BY MS. SINGER:

17 Q. Okay. All right. I'd like to
18 turn your attention to Section 5126, which is
19 Bates number ending 301.

20 And I'm sorry, the Bates number
21 for this document is CAH_MDL_PRIOR
22 PRODUCTION_DEA07_01176247.

23 All right. So turning to 301,
24 which I think has been tabbed in your copy,
25 Mr. Prevoznik.

1 A. Yep.

2 Q. All right. Can you read the
3 third paragraph beginning "registrants"?

4 A. "Registrants who routinely
5 report suspicious orders, yet fill these
6 orders with reason to believe they are
7 destined for the illicit market, are
8 expressing an attitude of irresponsibility
9 that is a detriment to the public health and
10 safety as set forth in 21 USC 823 and 824."

11 Q. And 21 USC 823 and 824 the
12 Controlled Substances Act?

13 A. Yes.

14 Q. Okay. And does that statement
15 that you just read accurately reflect the
16 policy of the DEA in 1990?

17 A. Yes.

18 Q. And has that remained true
19 since then?

20 A. Yes.

21 Q. Okay. And then read from there
22 "suspicious orders"?

23 A. "Suspicious orders include
24 those which are in excess of legitimate
25 medical use or exhibit characteristics

1 leading to possible diversion, such as orders
2 of unusual size, unusual frequency, or those
3 deviating substantially from the -- from a
4 normal pattern."

5 Q. And keep going.

6 A. "The supplier can determine
7 whether the order is excessive by checking
8 their own sales and establishing the average
9 amount of controlled substances shipped to
10 registrants of the same apparent size in a
11 particular geographic area. If the customer
12 exceeds this threshold, the request should be
13 viewed as suspicious."

14 Q. One more sentence.

15 A. "This activity over extended
16 periods of time would lead a reasonable
17 person to believe that controlled substances
18 possibly are being diverted."

19 Q. And does the passage you just
20 read again reflect the DEA's policy?

21 A. Yes.

22 MR. EPPICH: Form.

23 QUESTIONS BY MS. SINGER:

24 Q. And has that policy remained
25 the same since 1990 when this manual was

1 issued?

2 MS. FUMERTON: Object to form.

3 THE WITNESS: Yes.

4 (Prevoznik Plaintiff's Exhibit
5 P34 marked for identification.)

6 QUESTIONS BY MS. SINGER:

7 Q. Okay. Now, moving to the next
8 version of the -- of the Diversion
9 Investigators Manual, we're going to mark
10 that Exhibit 34.

11 And, Mr. Prevoznik, we only
12 have a piece of that manual.

13 Do you recognize the document
14 that I've just shown you as Exhibit 34?

15 A. Yes.

16 Q. And what do you recognize that
17 document to be?

18 A. As being a section from our --
19 the Diversion Investigators Manual.

20 Q. Okay.

21 A. DEA.

22 Q. And with respect to its
23 provisions on suspicious orders, which are
24 the first paragraph of Section 5126, is that
25 the same as what you just read previously?

1 A. I'm sorry, which paragraph?

2 MR. EPPICH: Object to form.

3 THE WITNESS: "Registrants"?

4 QUESTIONS BY MS. SINGER:

5 Q. I'm sorry. I don't have it up
6 on my monitor, so...

7 MS. MAINIGI: Counsel, may I
8 ask why this document is not
9 Bates-stamped?

10 MS. SINGER: Excuse me?

11 MS. MAINIGI: Why is this
12 document not Bates-stamped?

13 MS. SINGER: I don't know.
14 Because it came from the DEA. I think
15 the reliance materials for
16 Mr. Prevoznik.

17 MS. MAINIGI: Is that in fact a
18 representation you're making?

19 MS. SINGER: Excuse me?

20 MS. MAINIGI: Is that in fact a
21 representation that you know for
22 certain, or are you guessing?

23 MS. SINGER: So you can ask
24 your questions in your time.

25

1 QUESTIONS BY MS. SINGER:

2 Q. Mr. Prevoznik, just to clarify
3 for Cardinal's counsel's benefit, do you
4 recognize this from the materials you
5 reviewed in preparation for your deposition?

6 A. Yes.

7 Q. Okay. And do you know if this
8 was part of the binder that was provided to
9 counsel in advance of your deposition?

10 A. Yes.

11 Q. Okay. So can you read aloud
12 that first paragraph?

13 A. "Registrants are required to
14 inform DEA of suspicious orders in accordance
15 with 21 CFR 1301.74(b). DEA field offices
16 are not to approve or disapprove supplier
17 shipments of controlled substances. The
18 responsibility for making the decision to
19 ship rests with the supplier. An exception
20 to this occurs when a supplier" --

21 Q. You can stop there.

22 A. Okay.

23 Q. All right. And the section you
24 just read, does that reflect DEA's policy?

25 MS. MAINIGI: Objection.

1 THE WITNESS: Yes.

2 QUESTIONS BY MS. SINGER:

3 Q. And do you know, by the way,
4 the date of this version of the Diversion
5 Investigators Manual?

6 A. I can tell from the -- there
7 was an update on 4/16 of 1996.

8 Q. Okay. And then if you go down
9 to the third paragraph, "Registrants who
10 routinely report suspicious orders," is that
11 the same language that you read previously?

12 MR. EPPICH: Object to form.

13 THE WITNESS: Yes.

14 (Prevoznik Plaintiff's Exhibit
15 P35 marked for identification.)

16 QUESTIONS BY MS. SINGER:

17 Q. Okay. All right. Let's turn
18 now to Exhibit 35.

19 All right. And this is --

20 MR. FINKELSTEIN: While this is
21 being handed out, since we talked
22 about the reliance materials, I note
23 that the witness doesn't have a copy
24 of his reliance materials in front of
25 him and that I ask that he be provided

1 with that at some point.

2 We left it with the court
3 reporter. That was his reliance
4 binder.

5 MS. SINGER: So because we have
6 a different court reporter, I don't
7 think we have it. If -- we can try to
8 muster an additional copy, but any
9 document I show him, we will have
10 today.

11 MR. FINKELSTEIN: Okay.

12 QUESTIONS BY MS. SINGER:

13 Q. All right. So Exhibit 35 is
14 the NWDA Controlled Substances Manual, Bates
15 number HDA_MDL_000219360.

16 Mr. Prevoznik, have you seen
17 that document before?

18 A. It looks familiar.

19 Q. Okay. Now, I want to show you
20 also -- we're going to mark this Exhibit 36.

21 (Prevoznik Plaintiff's Exhibit
22 P36 marked for identification.)

23 QUESTIONS BY MS. SINGER:

24 Q. Exhibit 36 is from a website.
25 It's titled "NWDA Develops DEA Compliance

1 Institute to Reduce Industry Exposure to
2 Fines."

3 All right. Giving you a second
4 to look at the document, I just want to read
5 aloud the first paragraph.

6 "In response to increasingly
7 complex regulations, aggressive enforcement
8 and the potential for fines, the National
9 Wholesale Druggists' Association, NWDA, has
10 developed an industry institute on DEA
11 compliance," continued.

12 Would you agree that the DEA
13 had been aggressively enforcing --

14 MS. MAINIGI: Objection to the
15 use of this document.

16 MS. SINGER: I haven't even
17 finished --

18 MS. MAINIGI: I'm sorry. Go
19 ahead.

20 MS. SINGER: -- a question.

21 MS. MAINIGI: Sorry.

22 QUESTIONS BY MS. SINGER:

23 Q. Would you agree that the DEA
24 was aggressively or actively enforcing the
25 Controlled Substances Act in 1997 when

1 this doc -- when this press release was
2 issued?

3 MS. MAINIGI: Objection to the
4 use of this document. Objection.
5 Foundation. Scope.

6 THE WITNESS: I'm not sure what
7 you mean by the term "aggressively."
8 We were doing our job, so that
9 wouldn't...

10 QUESTIONS BY MS. SINGER:

11 Q. All right. And then going down
12 to the third paragraph -- or fourth
13 paragraph -- you know what? We're going to
14 leave that one there. Let's move on. Let's
15 go back to the manual itself, Exhibit 34.

16 So I want to turn first to --

17 MR. FINKELSTEIN: 34 or 35?

18 THE WITNESS: 35?

19 QUESTIONS BY MS. SINGER:

20 Q. 35, thank you.

21 -- to Bates number 435, which
22 is tabbed in your copy. It's titled
23 "Suspicious Orders - Controlled Substances."

24 Let me know when you've found
25 it.

1 A. Yep, I'm good.

2 Q. Okay.

3 MS. MAINIGI: I'm sorry,
4 Counsel, what's the page number?

5 MS. SINGER: 435.

6 QUESTIONS BY MS. SINGER:

7 Q. It says there, "Distributors
8 are responsible for designing and operating a
9 system that will disclose to the distributor
10 suspicious orders."

11 Do you agree that that is the
12 distributor's responsibility?

13 A. Yes.

14 Q. Okay. And then the note, "Many
15 distributors have been cited for failing to
16 establish and maintain such a system."

17 Is that also accurate?

18 A. Yes.

19 MS. MAINIGI: Objection.

20 MR. EPPICH: Form.

21 QUESTIONS BY MS. SINGER:

22 Q. Move to the next paragraph.
23 "Distributor establishing suspicious order
24 criteria. Distributors should establish
25 written criteria of what constitutes a

1 suspicious order. DEA leaves it to the
2 distributor to make this determination. The
3 key for the distributor is to establish
4 reasonable criteria based upon customer
5 purchasing patterns and then to adhere to
6 them in monitoring orders."

7 Does that several-step passage
8 that I just read accurately reflect a
9 distributor's duties under the CSA?

10 MS. MAINIGI: Objection.

11 Foundation. Scope. Form.

12 MR. EPPICH: Objection.

13 THE WITNESS: Yes.

14 QUESTIONS BY MS. SINGER:

15 Q. And do you see in this
16 description of suspicious order criteria any
17 expression of confusion or lack of clarity
18 about what a suspicious order is?

19 MR. EPPICH: Object to form.

20 MS. MAINIGI: Objection.

21 Foundation.

22 THE WITNESS: No.

23 QUESTIONS BY MS. SINGER:

24 Q. And then moving to the next
25 page, Bates number 436, you see the bullet

1 that begins, "Establish trigger levels"?

2 About middle of the page.

3 A. Yes.

4 Q. Okay. So it says here,

5 "Establish trigger levels, close quote, that

6 only kick out purchasers buying substantially

7 above the average for an item. The trigger

8 level is established by multiplying the

9 calculated average by an arbitrary factor.

10 It is recommended that at the outset three

11 times the average be used for ARCOS items and

12 four times the average for non-ARCOS items."

13 Do you see where I've just

14 read?

15 A. Yes.

16 Q. Okay. Is it DEA's position

17 that a fixed multiplier is a sufficient

18 system to identify suspicious orders?

19 MR. EPPICH: Object to form.

20 MS. MAINIGI: Foundation.

21 Scope.

22 THE WITNESS: Could you please

23 repeat it?

24 MS. SINGER: Yes.

25 QUESTIONS BY MS. SINGER:

1 Q. Is it DEA's position that a
2 fixed multiplier of order levels is
3 sufficient as a system to identify suspicious
4 orders?

5 MR. EPPICH: Object to form.

6 THE WITNESS: It could be one
7 criteria, but it can't be the only
8 one.

9 QUESTIONS BY MS. SINGER:

10 Q. Okay. And it says here, if you
11 keep reading on, "After the monitoring
12 program has been tested with live data and
13 the results analyzed, it may be necessary to
14 revise the factors."

15 Is it DEA's position that
16 distributors have an obligation to make sure
17 that any trigger or threshold they use
18 actually identifies suspicious orders?

19 MS. MAINIGI: Objection.

20 MR. FINKELSTEIN: Object to
21 form.

22 MS. MAINIGI: Form. Scope.

23 THE WITNESS: Yes.

24 QUESTIONS BY MS. SINGER:

25 Q. Okay. Moving next to Bates

1 number 437. Do you see the note is -- why
2 don't you go ahead and read that note.

3 "It is DEA's position."

4 A. "It is DEA's position that
5 after-the-fact monitoring program as
6 previously described, whether computer or
7 manual, does not relieve the distributor of
8 responsibility for policing individual orders
9 that appear excessive."

10 Q. Keep going.

11 A. "In these situations, DEA
12 should be notified before the order is
13 shipped, and a copy of all such orders should
14 be maintained in the distributor's suspicious
15 orders file, with a notation reflecting the
16 date and person contacted at DEA as well as
17 any guidance received."

18 Q. Go ahead and finish the
19 paragraph, please.

20 A. "The file also should indicate
21 whether the order was shipped. DEA usually
22 leaves the responsibility for determining
23 whether to ship to the distributor."

24 Q. And does this statement that
25 you just read from the NWDA manual of 1997

1 accurately describe the DEA's position on
2 what distributors should be -- or what
3 registrants should be doing?

4 MS. MAINIGI: Objection.

5 THE WITNESS: Yes.

6 QUESTIONS BY MS. SINGER:

7 Q. All right. And then I want you
8 to turn to the chemical control program at
9 Appendix L. So that, I think, should be
10 marked by the last tab. Nope. Nope.
11 There's one more, I'm sorry. So L6, yes,
12 which is Bates number 571.

13 Do you see the heading there
14 "Suspicious Orders"?

15 MR. FINKELSTEIN: 571. 69, 71.

16 THE WITNESS: Okay.

17 QUESTIONS BY MS. SINGER:

18 Q. All right. So the heading
19 there says, "Suspicious Orders," but it's
20 under 21 CFR 1310.05, correct?

21 A. Correct.

22 Q. And that's the provision that
23 relates to suspicious orders of List I
24 chemicals; is that correct?

25 A. Correct.

1 Q. Okay. And there it -- the
2 first sentence reads, "DEA has not provided a
3 clear definition of what constitutes a
4 suspicious order."

5 Now that relates to a
6 suspicious order of List I chemicals,
7 correct?

8 A. Correct.

9 Q. Okay. And there NWDA is saying
10 we don't have a clear definition, correct?

11 A. Correct.

12 Q. And we didn't see that earlier
13 in the manual, correct?

14 A. Correct.

15 Q. All right. Then let's move to
16 Appendix M, which is one more page. Bates
17 number 574, number 7: "What does DEA
18 consider to be a suspicious order?"

19 And if you can read that first
20 sentence?

21 A. "A registrant must report a
22 suspicious order for controlled substances,
23 which DEA defines as an order of unusual
24 size, orders deviating substantially from a
25 normal pattern and orders of unusual

1 frequency."

2 Q. Okay. Keep going all the way
3 to the end of that paragraph.

4 A. 21 CFR 1301.74(b).
5 "Registrants should set thresholds as a first
6 step in identifying potential suspicious
7 orders. However, registrants should refrain
8 from reporting all orders above the threshold
9 without a further review of the order or
10 customer. DEA expects that registrants will
11 only report orders that the registrant has
12 determined to be truly suspicious."

13 Q. And does the section you just
14 read reflect the policy of the DEA that
15 registrants should be reporting orders that
16 it deems suspicious?

17 MS. MAINIGI: Objection.

18 THE WITNESS: Yes.

19 (Prevoznik Plaintiff's Exhibit
20 P37 marked for identification.)

21 QUESTIONS BY MS. SINGER:

22 Q. All right. Let's move next to
23 Exhibit 37. We have a lot of paper today.

24 Exhibit 37 is Bates number

25 CAH_MDL_PRIOR PRODUCTION_DEA07_01178834, and

1 it's titled "DEA Compliance Manual, Cardinal
2 Health."

3 Mr. Prevoznik, have you seen
4 this document before?

5 A. No.

6 Q. Okay. I just want to point you
7 to a few pages. Let's turn first to
8 Bates number 880, which is also tabbed in
9 your copy.

10 Tell me when you're there.

11 A. I'm there.

12 Q. Okay. So it says, "Complying
13 with 21 CFR 1301.74(b) is a two-step process.
14 First, each Cardinal division submits to DEA
15 on a monthly basis an ingredient limit
16 report."

17 Have I read that correctly?

18 A. Yes.

19 Q. Okay. And then it goes down to
20 the next paragraph. "Second, on a daily
21 basis, cage and vault personnel" --

22 Do you know what that means?

23 A. Yes.

24 Q. What is that?

25 A. It's the person -- the people

1 that were -- that are authorized to work in
2 the cage or the vault, which are the secure
3 areas that contain the controlled substances.

4 Q. Okay.

5 -- "should be policing and
6 identifying individual orders that appear
7 excessive in relation to what other customers
8 are buying and/or the customer's purchase
9 history. In most situations, DEA should be
10 notified, if possible, before the order is
11 shipped, and a copy of all such orders should
12 be maintained in the division's suspicious
13 order file, along with a regulatory agency
14 contact form, Form 1, noting any specific
15 instructions from DEA."

16 Have I read that correctly?

17 A. Yes.

18 Q. Okay. And does this Cardinal
19 compliance manual accurately reflect a
20 registrant's obligation to notify DEA before
21 a suspicious order is shipped?

22 MS. MAINIGI: Objection.

23 Outside the scope of the Touhy
24 authorization. Form. Foundation.

25 THE WITNESS: Well, the

1 regulations require immediately upon
2 discovery, so it's not...

3 QUESTIONS BY MS. SINGER:

4 Q. Okay. If that was added, that
5 they should be notified -- that the DEA
6 should be notified immediately before a
7 suspicious order is shipped, would that be
8 accurate?

9 MS. MAINIGI: Objection -- same
10 objections.

11 THE WITNESS: Yes.

12 QUESTIONS BY MS. SINGER:

13 Q. Okay. And would DEA expect
14 that a registrant would remain -- excuse me,
15 would maintain copies of a suspicious order
16 reported to the DEA?

17 A. Yes.

18 Q. Let's turn then to the next
19 tab, which is -- oh, nope, we don't need to
20 do that. Never mind.

21 All right. Let's go back to
22 the slides we started with.

23 So, Mr. Prevoznik, we went
24 through the NWDA suspicious order monitoring
25 system, the seminar report that you went over

1 with Mr. Farrell was skipped over this time,
2 the DEA Diversion Investigators Manual, the
3 NWDA Controlled Substances Manual in 1997 and
4 Cardinal's compliance manual.

5 In each of those manuals, just
6 to be clear, was it true that DEA and the
7 industry recognized that suspicious orders
8 must be reported immediately when they are
9 discovered, not after they are shipped?

10 MS. MAINIGI: Objection.

11 Outside the scope of the Touhy
12 authorization. Foundation. Form.

13 THE WITNESS: Yes.

14 QUESTIONS BY MS. SINGER:

15 Q. And that suspicious -- that
16 orders that a registrant identifies as
17 suspicious cannot be shipped; is that
18 correct?

19 MS. MAINIGI: Objection. Form.
20 Foundation.

21 THE WITNESS: Correct.

22 QUESTIONS BY MS. SINGER:

23 Q. All right. Now, we think about
24 suspicious orders under CFR 1301.74, but the
25 registrant that ships suspicious orders also

1 fails to maintain effective controls to
2 prevent diversion; is that correct?

3 MR. MAHADY: Objection. Form.
4 Objection. Foundation. Calls for a
5 legal conclusion.

6 THE WITNESS: Correct.

7 QUESTIONS BY MS. SINGER:

8 Q. And would it make sense to DEA
9 that a registrant could identify an order as
10 suspicious, report it to the DEA and then
11 send it out to be sold or used?

12 MR. EPPICH: Objection. Form.
13 Calls for a legal conclusion.

14 THE WITNESS: And not do
15 anything to relieve the suspicion?

16 QUESTIONS BY MS. SINGER:

17 Q. That's right.

18 A. No, they shouldn't --

19 MR. EPPICH: Objection. Form.

20 QUESTIONS BY MS. SINGER:

21 Q. Can you say your answer again?

22 A. Could you repeat your question?

23 Q. Would it make sense to the DEA
24 that a registrant could identify an order as
25 suspicious, report it to the DEA, not dispel

1 their suspicion, and then go ahead and ship
2 it so that it could be sold or used?

3 MR. EPPICH: Object to form.

4 Calls for a legal conclusion.

5 MS. MAINIGI: Incomplete
6 hypothetical. Outside the scope.

7 THE WITNESS: No, it would not
8 be correct.

9 QUESTIONS BY MS. SINGER:

10 Q. Why?

11 A. Because they're not maintaining
12 effective controls over diversion.

13 MS. MAINIGI: Same objections.

14 QUESTIONS BY MS. SINGER:

15 Q. And what happens if they go
16 ahead and just ship that suspicious order?

17 MS. MAINIGI: Same objections.

18 MR. EPPICH: Object to the
19 form. Calls for speculation.

20 THE WITNESS: Well, it's --
21 there was a -- there was a reason it
22 triggered the suspicion, so the
23 possibility or potential for it to be
24 diverted into the illicit market is
25 enhanced because it triggered a

1 suspicious order within their system.

2 So that being the underlying
3 cause for it to be triggered, that --
4 the potential for it to be diverted,
5 now it's going -- the potential now is
6 greater that it's going into the
7 public and is going to affect the
8 public health and safety.

9 QUESTIONS BY MS. SINGER:

10 Q. Okay. And would going ahead
11 and shipping suspicious orders demonstrate an
12 attitude of irresponsibility, which I think
13 is the language of the Diversion
14 Investigators Manual, to the detriment of the
15 public health?

16 MS. MAINIGI: Objection.

17 Outside the scope of Touhy
18 authorization. Form.

19 MR. EPPICH: Objection.

20 THE WITNESS: Yes.

21 QUESTIONS BY MS. SINGER:

22 Q. And has that always been true,
23 that shipping a suspicious order is a failure
24 of effective controls to prevent diversion?

25 MR. MAHADY: Objection to form.

1 Objection to foundation.

2 THE WITNESS: Yes.

3 (Prevoznik Plaintiff's Exhibit
4 P38 marked for identification.)

5 QUESTIONS BY MS. SINGER:

6 Q. Now, one of the -- during the
7 first or second day of your deposition -- and
8 let's turn to your deposition. I'm sure just
9 what you want to relive.

10 All right. So we'll mark this
11 as Exhibit 38.

12 And, Mr. Prevoznik, can I
13 direct you -- and this is the deposition of
14 Tom Prevoznik, April 17, 2019.

15 All right. And if you could
16 turn to page 171. All right. And I want to
17 direct your attention to the middle of the
18 page where you testify: "It was a business
19 decision on whether to ship or not ship, that
20 we, DEA, were not going to direct a
21 registrant don't ship or not ship at that
22 time."

23 Do you see where I am?

24 MS. FUMERTON: Objection.

25 Form.

1 THE WITNESS: Yes.

2 QUESTIONS BY MS. SINGER:

3 Q. Okay. And then if you turn the
4 page -- I'm sorry. At the bottom of
5 page 171, because -- so in 7, it was clear
6 that you were now directing registrants: Do
7 not ship.

8 And you said, right, because of
9 the Internet.

10 And then there's a question:
11 "And prior to December 2007, it was a
12 business decision by each registrant
13 recognizing what their own obligations were,
14 correct?"

15 MR. EPPICH: Object to form.

16 THE WITNESS: Yes.

17 QUESTIONS BY MS. SINGER:

18 Q. Have I read that accurately?

19 A. Yes.

20 Q. And I just want to be clear.
21 Between -- before and after 2007, was it
22 always the policy of the DEA that registrants
23 could not ship suspicious orders?

24 MR. EPPICH: Object to form.

25 MS. MAINIGI: Objection. Form.

1 Testimony speaks for itself.

2 THE WITNESS: Yes.

3 MR. MAHADY: Foundation.

4 QUESTIONS BY MS. SINGER:

5 Q. And when you talk about a
6 change in 2007, you go on to say at the
7 bottom of 172, "Well, I don't know if there
8 was confusion or not because the -- quite a
9 few registrants continue to do what they
10 continue to do, which was continue to sell,
11 to ignore suspicious orders, and they
12 continue to sell huge volumes down the line
13 through retail."

14 Do you see what I've just read?

15 A. Yes.

16 Q. And I've read that accurately?

17 A. Yes.

18 Q. And is that the change you're
19 referring to in 2007, was DEA's recognition
20 that registrants continued to sell suspicious
21 orders?

22 MS. MAINIGI: Objection.

23 Testimony speaks for itself.

24 THE WITNESS: Yes. Because
25 when we met with them in 2005, we

1 showed them their own data and said,
2 "These are the things that we see,
3 that we see as very suspicious."

4 So we were telling the
5 registrants up front, "Look, there is
6 a problem. This is what we're
7 seeing."

8 And then they would say, "Yes,
9 we want to be -- we want to fix this."

10 And then we continued to see
11 those same things continue for some of
12 them. Some of them did correct it,
13 but some of them continued to go and
14 sell those things.

15 QUESTIONS BY MS. SINGER:

16 Q. Okay. And then continuing on
17 in your testimony, page 184, you're talking
18 in the middle of the page about the
19 subjective of shipping, of determining a
20 suspicious order.

21 Do you see where I am in the
22 middle of the page?

23 A. Yes.

24 Q. And Cardinal's counsel,
25 Ms. Mainigi, asked you: "Because it's

1 subjective," right?

2 Do you see where I am? Towards
3 the bottom of the page?

4 A. Yes.

5 Q. And then on the next page you
6 answered: "WITNESS: Yeah, it can be
7 subjective." Top of page 185.

8 Do you see where I am?

9 A. Yes.

10 Q. Okay. And I want to make sure
11 that your testimony is clear. When you say
12 whether a suspicious order is subjective, do
13 you mean that it varies from case to case, or
14 it depends on who's looking at it?

15 MS. MAINIGI: Objection to
16 form.

17 THE WITNESS: Both, really. It
18 depends who's looking at it and
19 what system do they have that's
20 triggering the suspicious order. So
21 it's whatever that registrant
22 designed, which is specific to that
23 registration.

24 QUESTIONS BY MS. SINGER:

25 Q. Right.

1 But a suspicious order is a
2 suspicious order that's an order of unusual
3 size -- you can say it better than I can, so
4 please go ahead.

5 MS. MAINIGI: Objection. Form.
6 Foundation.

7 THE WITNESS: Unusual --
8 unusual size, deviating from a --
9 substantially deviating from a normal
10 pattern, and unusual frequency.

11 QUESTIONS BY MS. SINGER:

12 Q. Okay. And that's universally
13 factually true, correct?

14 MS. MAINIGI: Objection.
15 Foundation. Vague. Outside scope.

16 THE WITNESS: Correct. And
17 it's disjunctive. So it could be one,
18 it could be two, it could be other
19 things that we've given guidance on.

20 We gave guidance in the
21 distributor initiative when we went
22 through the various red flags. We put
23 them in guidance letters as well -- or
24 not guidance, reiteration of the
25 regulations in 2006 and 2007 letters

1 from Mr. Rannazzisi.

2 QUESTIONS BY MS. SINGER:

3 Q. And those criteria don't vary
4 from registrant to registrant, correct?

5 MR. EPPICH: Object to form.

6 Vague.

7 THE WITNESS: Correct.

8 QUESTIONS BY MS. SINGER:

9 Q. And what differs is whether an
10 order triggers a suspicious {sic} based on a
11 customer's history, their buying patterns,
12 frequency, et cetera, correct?

13 MR. EPPICH: Object to form.

14 Vague.

15 THE WITNESS: Yes, as well as
16 the registrants, have they made any
17 changes to the system.

18 (Prevoznik Plaintiff's Exhibit
19 P39 marked for identification.)

20 QUESTIONS BY MS. SINGER:

21 Q. Okay. Let's turn very quickly
22 to the industry compliance guidelines.

23 All right. I'm going to show
24 you what's been marked as Exhibit 39.

25 And this is Bates number

1 CAH_MDL2804_00988458.

2 Mr. Prevoznik, have you seen
3 this document before?

4 A. Yes.

5 Q. Okay. And do you recognize
6 this to be the Healthcare Distribution
7 Management Association's industry compliance
8 guidelines?

9 A. Yes.

10 Q. Okay. And do you know -- I
11 don't know if they have a date on them, but
12 does it sound right that they were issued in
13 2008?

14 MR. EPPICH: Objection.

15 Foundation. Calls for speculation.

16 QUESTIONS BY MS. SINGER:

17 Q. Or do you know what year they
18 were issued?

19 A. I don't know.

20 Q. Okay.

21 A. I don't know.

22 Q. Okay. And if you look at the
23 first page, the third paragraph: "At the
24 center of a sophisticated supply chain,
25 distributors are uniquely situated to perform

1 due diligence in order to help support the
2 security of the controlled substances they
3 deliver to their customers."

4 Do you see what I've just read?

5 A. Yes.

6 Q. And does the DEA agree with
7 that statement?

8 A. Yes.

9 MS. MAINIGI: Objection.

10 QUESTIONS BY MS. SINGER:

11 Q. And did the DEA approve these
12 industry compliance guidelines?

13 A. No.

14 Q. Now, I just want to go through
15 some specifics with you very briefly, I hope,
16 to see if the DEA agrees that these elements
17 comply with the Controlled Substances Act.
18 Let's start with Bates number 461.

19 Does the DEA agree that a
20 registrant should investigate a customer
21 before agreeing to ship them controlled
22 substances?

23 MS. MAINIGI: Objection.

24 MR. EPPICH: Objection. Form.

25 THE WITNESS: Am I supposed to

1 be looking at something here or --

2 QUESTIONS BY MS. SINGER:

3 Q. No, just a general statement.

4 A. Oh, okay.

5 MR. EPPICH: Object to form.

6 QUESTIONS BY MS. SINGER:

7 Q. Do you want me to repeat the
8 question, or do you have it?

9 A. No. Repeat it.

10 Q. Does the DEA agree that a
11 registrant should investigate a customer
12 before agreeing to ship them controlled
13 substances?

14 MR. EPPICH: Object to form.

15 THE WITNESS: What do you mean
16 by the term "investigate"? Know who
17 they are?

18 QUESTIONS BY MS. SINGER:

19 Q. That they should know their
20 customer.

21 MR. EPPICH: Object to form.

22 THE WITNESS: Yes.

23 QUESTIONS BY MS. SINGER:

24 Q. Okay. And in this guide, it
25 lays out certain elements, including -- if

1 you look towards the bottom of the page under
2 the information-gathering step, would
3 include -- I'm sorry, let's start at the top
4 of the page.

5 Under the first paragraph,
6 Introduction: "Before opening an account" --
7 do you see where I am?

8 A. Yes.

9 Q. -- "the distributor should,
10 one, obtain background information on the
11 customer and the customer's business; review
12 that information carefully and, where
13 appropriate, verify that information; and
14 independently investigate the potential
15 customer."

16 Do you see what I've just read?

17 A. Yes.

18 Q. And does the DEA agree that
19 those are appropriate and necessary steps for
20 a registrant to take before shipping
21 controlled substances?

22 MR. EPPICH: Object to form.

23 THE WITNESS: Yes.

24 QUESTIONS BY MS. SINGER:

25 Q. Okay. And then moving down the

1 page, second bullet talks about a background
2 questionnaire.

3 Do you see that?

4 A. Yes.

5 Q. And that should cover the
6 average number of prescriptions filled each
7 day, average number of CS item prescriptions
8 filled each day.

9 Do you see where I am?

10 A. Yes.

11 Q. And CS probably means
12 controlled substances, yes?

13 MR. EPPICH: Objection.

14 Foundation. Calls for speculation.

15 THE WITNESS: Yes. In my
16 experience, yes.

17 QUESTIONS BY MS. SINGER:

18 Q. Okay. And then percentage of
19 controlled substances purchased compared to
20 overall purchases?

21 A. Yes.

22 Q. Would the DEA agree that those
23 are things that a registrant should be
24 looking at before shipping controlled
25 substances to a new customer?

1 MR. EPPICH: Object to form.

2 THE WITNESS: Yes.

3 QUESTIONS BY MS. SINGER:

4 Q. All right. And turning to the
5 next page, identify -- bottom bullet:

6 "Identification of physicians and other
7 treatment centers that are the potential
8 customer's most frequent prescribers or
9 highest purchasing doctors."

10 Do you see where I am?

11 A. Yes.

12 Q. And is that something that a
13 registrant should be doing as well?

14 MR. EPPICH: Object to form.

15 THE WITNESS: Yes.

16 QUESTIONS BY MS. SINGER:

17 Q. Okay. Turning to the next
18 page, independent investigation, subheading
19 D, it says at the first line, "The
20 distributor should independently investigate
21 the potential customer as follows:" Checking
22 with the local DEA office, state oversight
23 authorities, DEA website and Federal
24 Register, and conducting an Internet search.

25 Do you see each of those

1 elements?

2 A. Yes.

3 Q. And does the DEA agree that
4 those are things that a responsible
5 registrant should be doing before shipping
6 controlled substances to a customer?

7 MS. MAINIGI: Objection. Form.
8 Foundation. Vague.

9 THE WITNESS: Yes.

10 QUESTIONS BY MS. SINGER:

11 Q. And merely checking to see
12 whether a customer has a DEA registration,
13 would that be sufficient due diligence or
14 knowing your customer?

15 MR. EPPICH: Object to form.
16 Calls for a legal conclusion.

17 THE WITNESS: No.

18 QUESTIONS BY MS. SINGER:

19 Q. And it says here under
20 Additional Recommendations and Documentation,
21 the third bullet, "The performance and
22 results of all steps in the customer review
23 process should be fully documented as to each
24 potential customer, and such documentation
25 should be retained in an appropriate file."

1 Do you see what I've just read?

2 A. Yes.

3 Q. And does the DEA also agree
4 that that is an appropriate element, that
5 documenting due diligence or knowing your
6 customer is an appropriate element of that
7 program?

8 MR. EPPICH: Object to form.

9 Calls for a legal conclusion.

10 THE WITNESS: Yes.

11 QUESTIONS BY MS. SINGER:

12 Q. All right. Turning to 465, so
13 two pages ahead, you see the section Develop
14 Thresholds to Identify Orders of Interest?

15 A. Yes.

16 Q. Okay. So it says here that
17 distributors -- I'm down at the second set of
18 bullets, the bottom bullet: "Thresholds for
19 all new customer accounts should be
20 established at the lowest level indicated by
21 information obtained during the know your
22 customer due diligence review."

23 Do you see where I've just
24 read?

25 A. Yes.

1 Q. And does the DEA agree that
2 that is appropriate?

3 MR. EPPICH: Object to form.

4 MS. MAINIGI: Objection.

5 THE WITNESS: I guess my
6 concern would be that if you're --
7 what is the lowest level? Is it what
8 the customer is reporting what they
9 said they ordered or is it -- you
10 know, it could be like really a large
11 amount, or is the registrant saying
12 this is what we are going to say is
13 the lowest amount.

14 So I have a little trouble with
15 that one.

16 QUESTIONS BY MS. SINGER:

17 Q. Okay. So just making sure that
18 we get this clear for the jury, the amount
19 that a customer reports may be too high,
20 correct?

21 MR. EPPICH: Object to form.

22 MS. MAINIGI: Objection.

23 MR. EPPICH: Incomplete
24 hypothetical.

25 THE WITNESS: Yes.

1 QUESTIONS BY MS. SINGER:

2 Q. And the registrant should be
3 making its own judgment about what is not
4 suspicious for a particular customer and not
5 just accepting what they've previously
6 ordered, correct?

7 MR. EPPICH: Object to form.

8 Calls for a legal conclusion.

9 THE WITNESS: Correct.

10 QUESTIONS BY MS. SINGER:

11 Q. And they shouldn't be building
12 in some excess above that level, correct?

13 MR. EPPICH: Object to form.

14 Calls for a legal conclusion.

15 THE WITNESS: Yes.

16 QUESTIONS BY MS. SINGER:

17 Q. All right. And then looking at
18 the section Cumulative Reviews/Thresholds,
19 the industry compliance guidelines also
20 indicate that "there should be a mechanism to
21 compare percentages of orders for controlled
22 substances, individual products and/or
23 families to orders of noncontrolled substance
24 prescription drugs so as to identify a shift
25 in a customer's business focus that may

1 warranty further review."

2 Do you see what I've just read?

3 A. Yes.

4 Q. And does the DEA agree that a
5 registrant should not just be looking at a
6 customer's controlled substances orders but
7 their controlled substance orders relative to
8 other products they're ordering?

9 MR. EPPICH: Object to form.

10 Calls for a legal conclusion.

11 THE WITNESS: Yes.

12 QUESTIONS BY MS. SINGER:

13 Q. All right. And then Bates
14 number 466 under E, the last sentence:
15 "Based on the distributor's knowledge of his
16 or her customer's overall drug purchasing
17 trends, information available from DEA and
18 elsewhere, distributors are encouraged to
19 allow for alternative criteria, in addition
20 to those incorporated into the electronic
21 system, to serve as indicators of an order of
22 interest."

23 Do you see what I've just read?

24 A. Yes.

25 Q. And is it DEA's view that --

1 and I think you testified to this earlier --
2 that a registrant should be looking at other
3 indicators of suspicion, not just an order
4 history? Correct?

5 MR. EPPICH: Object to form.

6 THE WITNESS: Yes.

7 QUESTIONS BY MS. SINGER:

8 Q. And is the DEA aware that
9 distributors have sales representatives or
10 account managers who visit pharmacies, for
11 instance?

12 MR. EPPICH: Object to form.

13 Foundation.

14 THE WITNESS: Yes.

15 MS. MAINIGI: Scope.

16 QUESTIONS BY MS. SINGER:

17 Q. And should distributors be
18 looking at the -- should they be
19 incorporating or factoring the observations
20 of their account managers or sales reps into
21 their evaluation of customers and their
22 orders?

23 MR. EPPICH: Object to form.

24 Calls for a legal conclusion.

25 Foundation.

1 THE WITNESS: Yes. But I would
2 also -- they're drivers as well,
3 because it's on a daily basis they're
4 in the pharmacies.

5 QUESTIONS BY MS. SINGER:

6 Q. Okay. All right. And then
7 looking at the bottom of the page, still at
8 Bates number 466, "The drug or drugs that
9 cause an order to become an order of interest
10 should not be shipped to the customer placing
11 the order while the order is an order of
12 interest."

13 Do you see what I've just read
14 there?

15 A. Yes.

16 Q. And do you understand that to
17 be saying that while an order is being
18 evaluated as to whether it's suspicious, it
19 should not be shipped?

20 A. Yes.

21 MS. MAINIGI: Objection. Form.

22 QUESTIONS BY MS. SINGER:

23 Q. And it -- again, that is the --
24 that is what the Controlled Substances Act
25 requires, correct?

1 MR. EPPICH: Object to form.

2 Calls for a legal conclusion.

3 MR. MAHADY: Foundation.

4 THE WITNESS: Correct.

5 QUESTIONS BY MS. SINGER:

6 Q. All right. Next page, the top
7 of the page: "It's recommended that the
8 distributor designate a person with suitable
9 training and experience to investigate orders
10 of interest."

11 Do you see what I've just read?

12 A. Yes.

13 Q. And does the DEA agree that a
14 registrant should have appropriately trained
15 and experienced compliance staff executing
16 its suspicious order monitoring and due
17 diligence process?

18 MR. EPPICH: Objection.

19 MS. MAINIGI: Objection. Form.

20 MR. EPPICH: Foundation.

21 THE WITNESS: Yes.

22 QUESTIONS BY MS. SINGER:

23 Q. All right. Bates number 468,
24 subsection D, Documentation, it says under
25 that, "All investigations should be fully

1 documented, and all records of the
2 investigation should be retained in an
3 appropriate location within the firm, such as
4 with other records relating to the particular
5 customer."

6 Does the DEA agree with that
7 element of a compliant suspicious order
8 monitoring program?

9 MR. EPPICH: Object to form.

10 Calls for a legal conclusion.

11 THE WITNESS: Yes.

12 QUESTIONS BY MS. SINGER:

13 Q. And in the middle of the next
14 paragraph: "The documentation should include
15 a clear statement of the final conclusion of
16 the investigation, including why the order
17 investigated was or was not determined to be
18 suspicious. That statement should be signed
19 and dated by the reviewer. Copies of any
20 written information provided by the customer
21 should also be retained as part of the
22 documentation of the investigation."

23 Does the DEA agree that's
24 appropriate?

25 MR. EPPICH: Objection to form.

1 Calls for a legal conclusion.

2 THE WITNESS: Yes.

3 QUESTIONS BY MS. SINGER:

4 Q. All right. Very last paragraph
5 on that page, "Orders that are determined to
6 be suspicious should be reported to DEA under
7 Section 1301.74(b) immediately upon being so
8 determined."

9 I think you've already
10 testified that that's a requirement, correct?

11 MR. EPPICH: Objection to form.

12 THE WITNESS: Correct.

13 QUESTIONS BY MS. SINGER:

14 Q. "It is assumed that the order
15 will continue to be placed on hold and/or
16 canceled once it has been identified as
17 suspicious."

18 Is that also consistent with
19 the DEA's interpretation of the Controlled
20 Substance Act's requirements?

21 MR. EPPICH: Object to form.

22 Calls for a legal conclusion.

23 THE WITNESS: Yes.

24 QUESTIONS BY MS. SINGER:

25 Q. Now, if the -- if an order is

1 identified as suspicious and not shipped but
2 held and then released the next month when a
3 threshold is reset, does the DEA believe that
4 the registrant is still shipping a suspicious
5 order?

6 MR. EPPICH: Object to form.
7 Calls for a legal conclusion and
8 incomplete hypothetical.

9 MS. MAINIGI: Outside the
10 scope.

11 THE WITNESS: Could you please
12 repeat that?

13 QUESTIONS BY MS. SINGER:

14 Q. Now, if an order is identified
15 as suspicious and not shipped but then held,
16 you know, not shipped, held until the next
17 month when a threshold resets, is that order
18 still suspicious?

19 MR. EPPICH: Object to form.
20 Calls for a legal conclusion and
21 incomplete hypothetical.

22 MR. FINKELSTEIN: Incomplete
23 hypothetical.

24 THE WITNESS: Yes.

25

1 QUESTIONS BY MS. SINGER:

2 Q. And should the registrant be
3 shipping that the next month?

4 MR. EPPICH: Object to form.

5 Calls for a legal conclusion.

6 QUESTIONS BY MS. SINGER:

7 Q. Without first dispelling the
8 suspicion?

9 MR. EPPICH: Object to form.

10 Calls for a legal conclusion.

11 Incomplete hypothetical.

12 THE WITNESS: Yes, they should
13 be relieving -- or ascertaining is
14 there suspicion or not.

15 QUESTIONS BY MS. SINGER:

16 Q. And not shipping unless they
17 eliminate the basis for that suspicion?

18 A. Correct.

19 MR. EPPICH: Object to form.

20 Calls for a legal conclusion.

21 Incomplete hypothetical.

22 QUESTIONS BY MS. SINGER:

23 Q. 469, sub F, Future Customer
24 Orders. "In instances where a distributor
25 concludes that an order is or remains

1 suspicious after conducting an investigation,
2 in addition to notifying DEA, it is
3 recommended that the distributor evaluate its
4 business relationship with the customer that
5 placed that order."

6 Do you see what I've just read?

7 A. Yes.

8 Q. "The distributor may consider
9 whether to subject future orders from that
10 same customer -- from that same customer for
11 the same drug code product or all controlled
12 substances to more rigorous scrutiny than was
13 applied before the determination that the
14 order is suspicious. The distributor may
15 also consider whether to cease filling all
16 future orders of that drug product code or
17 all controlled substances placed by that
18 customer."

19 Does the DEA agree that when a
20 registrant identifies a suspicious order,
21 they should also be looking more generally at
22 that customer?

23 MS. MAINIGI: Objection to
24 form.

25 THE WITNESS: Yes.

1 QUESTIONS BY MS. SINGER:

2 Q. And making a decision as to not
3 only whether to fill that order but to
4 continue filling orders for that customer?

5 MR. EPPICH: Object to form.

6 Calls for a legal conclusion.

7 THE WITNESS: Yes.

8 QUESTIONS BY MS. SINGER:

9 Q. All right. Bottom of page 469.
10 An endless document for one so short. It
11 says at the bottom bullet, "For example, the
12 distributor may identify information that
13 leads them to believe that a potential
14 customer, prior to entering a formal business
15 arrangement with that customer, may
16 intend" -- on the next page -- "to order
17 controlled substances -- controlled substance
18 products with a frequency, volume or other
19 indicator that could be considered
20 suspicious. In such instances, the
21 distributor should provide DEA with a report
22 of this information under 21 CFR
23 Section 1301.74(b)."

24 Do you see what I've just read?

25 A. Yes.

1 Q. And would the DEA agree that if
2 a distributor is evaluating a potential
3 customer, sees indications that it may be
4 engaged in diversion, it is not sufficient
5 for the distributor to simply not do business
6 with that customer, but that they should also
7 be reporting that customer -- that potential
8 customer to the DEA?

9 MR. EPPICH: Object to form.

10 Calls for a legal conclusion.

11 THE WITNESS: Yes.

12 QUESTIONS BY MS. SINGER:

13 Q. All right. Subsection B on
14 Bates number 470, under Correspondence For
15 Reporting, "It is recommended that all
16 correspondence to DEA containing reports of
17 suspicious orders should be sent registered
18 mail with a return receipt requested, by
19 electronic mail or by another system that
20 creates for the distributor a permanent
21 record that DEA has received the
22 notification."

23 Does the DEA agree with that?

24 MS. MAINIGI: Objection to
25 form.

1 THE WITNESS: Well, we have two
2 different things going on. We have
3 those that report to the field and
4 those that have been under an action
5 that is now dictated to go through
6 electronically to headquarters.

7 So, yes, if it's going to the
8 office, that would be a great way to
9 do it, to track that.

10 QUESTIONS BY MS. SINGER:

11 Q. Okay. And that C,
12 Documentation, "All additional contact with
13 DEA, either by telephone or in person, should
14 be documented, and a record of the contact
15 should be maintained."

16 Does the DEA agree with that?

17 A. Yes.

18 Q. And is it fair to say that the
19 DEA would agree that a registrant should be
20 maintaining records of suspicious orders they
21 report to the DEA?

22 MR. EPPICH: Object to form.

23 Calls for a legal conclusion.

24 Foundation.

25 THE WITNESS: Yes.

1 QUESTIONS BY MS. SINGER:

2 Q. So while registrants, in going
3 through all of these different elements of
4 the industry compliance guidelines, which
5 we're now thankfully finished with, would the
6 DEA agree that whatever suspicious order
7 monitoring algorithm or system that a
8 registrant uses, that all of these elements
9 we just went through are elements of a
10 responsible and compliant program to prevent
11 diversion?

12 MR. EPPICH: Object to form.

13 Calls for a legal conclusion.

14 THE WITNESS: Yes.

15 QUESTIONS BY MS. SINGER:

16 Q. All right.

17 MR. FINKELSTEIN: Why don't we
18 take a five-minute break.

19 MS. SINGER: Can I do one more
20 document that connects with this and
21 then --

22 MR. FINKELSTEIN: Okay. One
23 more.

24 MS. SINGER: Thank you.

25 (Prevoznik Plaintiff's Exhibit

1 P40 marked for identification.)

2 QUESTIONS BY MS. SINGER:

3 Q. All right. Mr. Prevoznik,
4 Exhibit 40 is entitled "Draft DEA Comments
5 From the 6-04-08 Meeting on Suspicious
6 Orders." It's Bates number
7 CAH_MDL2804_03234535.

8 Have you seen this document?

9 A. No.

10 Q. Okay. Do you see here at the
11 top of the document a list of DEA attendees?

12 A. Yes.

13 Q. And do you recognize those to
14 be people who have worked for the DEA?

15 A. Yes.

16 Q. Okay. And do you recognize the
17 HDMA attendees? Somebody from Williams &
18 Connolly, people identified as with HDMA?

19 A. I don't recognize the names.

20 Q. Okay. All right. If you go
21 down to the middle of the page, P.4,
22 Item 1.B, it says, "DEA was pleased to see
23 that the questionnaire would be notarized or
24 provided with the statement declaring that it
25 is true and correct. DEA does not want

1 changes but wants us to be aware that merely
2 obtaining a signed document isn't going to be
3 enough of a defense. Distributors will have
4 to do more to identify the pharmacy's
5 legitimacy."

6 Do you understand what this is
7 referring to?

8 MS. MAINIGI: Objection.

9 Foundation. Outside the scope of the
10 Touhy authorization.

11 THE WITNESS: I don't know what
12 question they're talking about.

13 QUESTIONS BY MS. SINGER:

14 Q. Okay. Would the DEA agree that
15 in addition to completing a question --
16 having a potential customer complete a
17 questionnaire before a registrant agrees to
18 ship them a controlled substance, that a
19 registrant has to verify that the answers to
20 that questionnaire are accurate and complete?

21 MR. EPPICH: Object to the
22 form. Calls for a legal conclusion.

23 THE WITNESS: Yes.

24 QUESTIONS BY MS. SINGER:

25 Q. And then turning to page 2 of

1 this document, which is Bates number 536, it
2 says, "DEA seemed to think that, quote,
3 thresholds, focus principally on volumes, and
4 they express the view that an exclusive or
5 even principal focus on volumes is
6 inadequate."

7 Is that consistent with the
8 testimony you've given that just using volume
9 thresholds aren't sufficient to identify
10 suspicious orders?

11 MR. FINKELSTEIN: The portion
12 you read isn't in front of the
13 witness.

14 Do you know where she's reading
15 from?

16 THE WITNESS: No.

17 QUESTIONS BY MS. SINGER:

18 Q. I'm sorry. It's the bottom of
19 page 536, the underscored language.

20 MS. FUMERTON: Object to form.

21 MR. EPPICH: Object to the
22 form. Calls for a legal conclusion.
23 Vague.

24 THE WITNESS: Sorry, can you
25 repeat it?

1 QUESTIONS BY MS. SINGER:

2 Q. Yeah.

3 Do you agree with that first
4 underlined sentence, "DEA seemed to think the
5 thresholds focus principally on volumes, and
6 they express the view that an exclusive or
7 even principal focus on volumes is
8 inadequate"?

9 A. Yes.

10 Q. Okay. They also want the
11 initial screen of orders to focus on, "A,
12 patterns of ordering, comparing the present
13 order to the past orders from the same
14 customers, including whether the frequency of
15 orders is suspicious; 2, orders are from
16 similar customers; and, 3, orders from the --
17 from other establishments of the same type in
18 the locale or region; and on, B, combinations
19 of controlled substances ordered."

20 Does DEA agree that that is
21 also a necessary element of monitoring for
22 suspicious orders?

23 MR. EPPICH: Object to the
24 form. Calls for a legal conclusion.

25 THE WITNESS: Yeah, I'm not --

1 the word "necessary," I mean, it's
2 very important. It's part of the
3 criteria that should be included.

4 QUESTIONS BY MS. SINGER:

5 Q. Okay. And then on Bates
6 number 538, looking at the highlighted
7 language toward the bottom of the page: "In
8 general" --

9 I want to make sure you see
10 where I am.

11 A. Yes.

12 Q. -- "DEA did not object to our
13 recommendation that the particular drug or
14 drugs that cause an order to be an order of
15 interest or a suspicious order should not be
16 shipped but other drugs can be. Their point
17 was that in some circumstances the connection
18 between that drug and another drug in the
19 order should lead the wholesaler not to ship
20 the other drug as well. Again, in their
21 view, looking at a volume order drug by drug
22 is not enough, and basing thresholds solely
23 on volume is not enough. Even an order for a
24 drug that does not meet a volume threshold
25 may be suspicious in light of other aspects

1 of the order."

2 Does DEA agree with that

3 statement?

4 MR. EPPICH: Object to the

5 form. Calls for a legal conclusion.

6 THE WITNESS: Yes.

7 QUESTIONS BY MS. SINGER:

8 Q. Okay. And then the final
9 section of this document, Bates number 539,
10 if you look at the bullets on the bottom of
11 the page, additional comments/points raised.

12 Do you see where I am?

13 A. Yes.

14 Q. "DEA was emphatic that if there
15 were questions about an order, the order
16 should not be shipped."

17 Do you agree with that
18 statement?

19 MR. EPPICH: Object to form.
20 Calls for a legal conclusion.

21 THE WITNESS: Yes.

22 QUESTIONS BY MS. SINGER:

23 Q. And why do you think the
24 "should not" is underscored there?

25 MR. EPPICH: Object to the

1 form. Foundation. Calls for
2 speculation.

3 MS. MAINIGI: Objection.
4 Foundation.

5 MR. FINKELSTEIN: Calls for
6 speculation.

7 MS. SINGER: You know what?
8 Withdrawn. Don't answer that.

9 QUESTIONS BY MS. SINGER:

10 Q. The next bullet, "They wanted
11 reports on all suspicious orders even if the
12 order was not shipped."

13 Does the DEA agree that
14 registrants should be reporting all
15 suspicious orders, even orders that aren't
16 shipped?

17 MR. EPPICH: Object to the
18 form. Calls for speculation. Calls
19 for a legal conclusion.

20 THE WITNESS: Yes.

21 QUESTIONS BY MS. SINGER:

22 Q. "Timeliness is very important.
23 DEA wants us to emphasize the need for rapid,
24 timely reporting."

25 Is that a point that DEA made

1 clear to registrants?

2 MR. MAHADY: Objection to form.

3 Objection to foundation.

4 MR. EPPICH: Calls for
5 speculation.

6 THE WITNESS: It's also
7 regulation upon discovery, so it's
8 immediately upon discovery.

9 QUESTIONS BY MS. SINGER:

10 Q. So that's a yes?

11 A. Yes.

12 MS. SINGER: Okay. All right.
13 Let's take a break.

14 VIDEOGRAPHER: We're going off
15 record. The time is 10:30.
16 (Off the record at 10:30 a.m.)

17 VIDEOGRAPHER: We're going back
18 on the record. Beginning of Media
19 File 3. The time is 10:45.

20 MR. FINKELSTEIN: Before we
21 resume, I just have a request of the
22 parties and of the special master as
23 well.

24 Since it appears that we are
25 deferring argument over the scope of

1 the Touhy authorization until sometime
2 later, we would ask that we be copied
3 on briefings regarding the scope of
4 the Touhy authorization and that we be
5 given an opportunity to respond.

6 MS. MAINIGI: Fine with us.

7 MR. FINKELSTEIN: And I ask
8 that those be e-mailed directly to
9 James Bennett.

10 MR. BENNETT: That's fine.

11 SPECIAL MASTER COHEN: So
12 stipulated.

13 MS. SINGER: All right. Are we
14 ready?

15 QUESTIONS BY MS. SINGER:

16 Q. All right. Mr. Prevoznik, on
17 the one hand, industry has complained that
18 you didn't give -- you, the DEA, didn't give
19 them enough guidance or the right kind of
20 guidance on identifying suspicious orders,
21 but then one of the lawyers in your first two
22 days of deposition suggested that the
23 Rannazzisi letters, those 2006, 2007 letters,
24 were improper and should have gone through a
25 rulemaking process.

1 Do you remember what I'm
2 referring to?

3 MR. EPPICH: Object to form.

4 MS. MAINIGI: Objection.

5 THE WITNESS: Yes.

6 QUESTIONS BY MS. SINGER:

7 Q. Okay. Is DEA able to swear
8 these positions, that you didn't give enough
9 guidance, but you also should have given more
10 guidance? I just said the same thing.

11 MR. EPPICH: Objection.

12 QUESTIONS BY MS. SINGER:

13 Q. Is the DEA able to swear those
14 positions, that the guidance you gave was
15 improper but you should have given more
16 guidance?

17 MR. EPPICH: Object to form.

18 Vague.

19 MS. MAINIGI: Outside the scope
20 also.

21 THE WITNESS: I'm not sure what
22 you're asking me.

23 QUESTIONS BY MS. SINGER:

24 Q. So when industry complains you
25 didn't give them enough guidance on

1 suspicious orders but also said that the
2 Rannazzisi letters were improper because they
3 didn't go through a rulemaking process, are
4 you able to reconcile those positions?

5 What should DEA have done?

6 MR. EPPICH: Object to form.

7 MS. MAINIGI: Objection.

8 Outside the scope of the Touhy
9 authorization. Improper hypothetical.

10 MR. FINKELSTEIN: I'll join the
11 scope objection.

12 You can answer if you
13 understand.

14 THE WITNESS: I'm still not
15 sure what you're asking.

16 MS. SINGER: Okay. Skip it.

17 QUESTIONS BY MS. SINGER:

18 Q. Okay. Let me ask it
19 differently.

20 Did the Rannazzisi letters, the
21 2006, 2007 letters, change the obligations of
22 registrants?

23 A. No.

24 MR. EPPICH: Object to form.

25 Calls for a legal conclusion.

1 QUESTIONS BY MS. SINGER:

2 Q. Did they reflect a new policy
3 or interpretation by DEA?

4 MR. EPPICH: Object to the
5 form.

6 THE WITNESS: No, we were just
7 being more proactive to get the
8 registrants to see this was what was
9 going on. That's why we did the
10 distributor initiatives, to show them
11 with their own data, these are the
12 anomalies that we were seeing and
13 explaining to them this is what we
14 saw, and you should be paying
15 attention to these as well.

16 So the guidance letter -- or
17 not the guidance. The reiteration of
18 what their legal obligations were,
19 both statutorily and regulatory, were
20 in those letters, and it was to stop
21 what was going on at that time.

22 QUESTIONS BY MS. SINGER:

23 Q. And "stop" meaning the --

24 A. The diversion of controlled
25 substances into the illicit market.

1 (Prevoznik Plaintiff's Exhibit
2 P41 marked for identification.)

3 QUESTIONS BY MS. SINGER:

4 Q. Okay. Showing you Exhibit 41.
5 Do you recognize this, Mr. Prevoznik, as one
6 of Joe Rannazzisi's letters from
7 September 27, 2006?

8 A. Yes.

9 Q. And turn to page 3 of that
10 letter, please.

11 Do you see a heading at the top
12 of the page, Circumstances That Might Be
13 Indicative of Diversion?

14 A. Yes.

15 Q. And does this letter then go
16 through a list of ten factors that
17 registrants might look to to determine
18 whether an order is suspicious?

19 MS. MAINIGI: Objection.

20 THE WITNESS: Are you talking
21 the middle 10 or the four above it?

22 QUESTIONS BY MS. SINGER:

23 Q. The 1 through 4 -- I'm sorry,
24 and then 1 through 10, so a total of 14.

25 A. Yes.

1 Q. Your math is better than mine.

2 And does this, in fact, reflect
3 information, clarification, that DEA provided
4 to registrants to help them identify
5 suspicious orders?

6 A. Yes.

7 Q. Okay.

8 MR. EPPICH: Object to form.

9 QUESTIONS BY MS. SINGER:

10 Q. All right. Now, many of the
11 registrants represented by counsel here are
12 sophisticated, multi-billion dollar
13 companies; is that correct?

14 MR. EPPICH: Object to form.

15 MS. MAINIGI: Object to form.

16 Scope.

17 MR. FINKELSTEIN: Hang on.

18 I'll join the scope objection.

19 You can answer.

20 QUESTIONS BY MS. SINGER:

21 Q. Does DEA believe that they
22 needed DEA to explain the rules to them?

23 MR. EPPICH: Object to form.

24 Argumentative.

25 MS. MAINIGI: Scope.

1 THE WITNESS: Well, I mean,
2 it's -- our job as DEA is as a
3 regulatory and as a law enforcement,
4 is to ensure that the right -- that
5 it's staying within the closest in the
6 distribution. So that's -- our job is
7 to investigate, detect and pro -- and
8 detect where this might be occurring.
9 So, I mean, that's what our job is.

10 QUESTIONS BY MS. SINGER:

11 Q. Okay. So let me ask it
12 slightly differently.

13 In your experience, did these
14 companies have lawyers and lobbyists to help
15 them explain the rules for preventing
16 diversion and reporting suspicious orders?

17 MR. EPPICH: Objection. Form.
18 Calls for speculation. Foundation.

19 MS. MAINIGI: Outside the
20 scope.

21 THE WITNESS: Yes.

22 QUESTIONS BY MS. SINGER:

23 Q. And do you think, does DEA
24 think, that the industry's failure to comply
25 with the Controlled Substances Act was due to

1 a failure to understand what the law required
2 of them?

3 MR. MAHADY: Objection. Form.

4 MS. MAINIGI: Foundation.

5 Scope.

6 MR. EPPICH: Objection. Calls
7 for a legal conclusion.

8 MR. FINKELSTEIN: Calls for
9 speculation.

10 THE WITNESS: No.

11 QUESTIONS BY MS. SINGER:

12 Q. And do you think that
13 industry's failure to comply with the
14 Controlled Substances Act and maintain -- and
15 the failure to maintain effective controls
16 was due to -- I'm sorry, let me say that
17 again.

18 Do you think that industry's
19 failure to maintain effective controls to
20 prevent diversion was based on a lack of
21 recognition that diversion imperils public
22 health and safety?

23 MR. EPPICH: Objection to form.
24 Foundation. Calls for a legal
25 conclusion.

1 MR. FINKELSTEIN: Calls for
2 speculation.

3 THE WITNESS: Can you please
4 repeat it?

5 QUESTIONS BY MS. SINGER:

6 Q. Yeah. I'll put it differently.

7 Do you think that the reason
8 that the industry didn't comply with the
9 rules is because they didn't understand what
10 would happen if they permitted the diversion
11 of controlled substances?

12 MR. EPPICH: Objection to form.
13 Calls for speculation.

14 MS. MAINIGI: Outside the scope
15 of the Touhy authorization.

16 MR. FINKELSTEIN: Calls for
17 speculation.

18 THE WITNESS: Can you give it
19 to me one more time? I'm just having
20 a little hard time interpreting.

21 QUESTIONS BY MS. SINGER:

22 Q. Do you think that industry
23 failed to understand that permitting the
24 diversion of controlled substances
25 jeopardizes public health and safety?

1 MR. EPPICH: Objection to form.

2 Calls for speculation. Scope.

3 MR. FINKELSTEIN: Same

4 objection.

5 THE WITNESS: Yes, I would

6 agree that they didn't.

7 QUESTIONS BY MS. SINGER:

8 Q. And put a different way,

9 because I've got a lot of negatives in there,

10 do you think industry understood that

11 diversion leads to negative consequences for

12 public health and safety?

13 MR. EPPICH: Object to form.

14 Calls for speculation. Legal

15 conclusion. Scope.

16 MS. MAINIGI: Foundation.

17 MR. FINKELSTEIN: Calls for

18 speculation.

19 THE WITNESS: I think they

20 obviously do now. I don't know at

21 that time that they realized how bad

22 it was getting.

23 QUESTIONS BY MS. SINGER:

24 Q. But they did understand that

25 the purpose of the controlled -- of the

1 closed system is to prevent diversion and
2 protect public safety and the public
3 interest?

4 MR. EPPICH: Objection to form.

5 MS. MAINIGI: Objection to
6 form. Outside the scope of the Touhy
7 authorization.

8 Special Master Cohen, I do
9 think that this entire line of
10 questioning where somehow the DEA is
11 supposed to define what industry was
12 thinking in some broad sense is
13 totally improper.

14 MR. EPPICH: Objection. Calls
15 for speculation.

16 MR. FINKELSTEIN: Join the
17 speculation objection.

18 SPECIAL MASTER COHEN:
19 Eventually there will be an
20 admissibility ruling on this. I'm not
21 going to preclude the questions from
22 being asked at this juncture.

23 QUESTIONS BY MS. SINGER:

24 Q. Did you answer the question,
25 that --

1 A. I'm not sure if I answered or
2 not.

3 Q. Okay. Let me ask one more.

4 Is the -- did the DEA, in the
5 Controlled Substances Act, make clear to
6 industry that the failure to prevent
7 diversion was a threat to public safety and
8 the public interest?

9 MR. EPPICH: Objection to form.
10 Foundation.

11 THE WITNESS: Yes, I think it's
12 established in 823 where it's part of
13 our -- part of the registrant that is
14 applying to be a registrant
15 understands that they have to maintain
16 effective controls. They have to
17 follow the state laws. They have to
18 not be convicted of, you know,
19 felonies or anything like that.

20 But also they also know that
21 these drugs themselves are scheduled
22 controlled substances for a particular
23 reason, because they're addictive,
24 psychologically and physically they're
25 addictive, so they know that these

1 drugs have these properties within
2 themselves.

3 So they would understand that
4 these drugs are categorized or
5 scheduled in that manner because they
6 have the potential to hurt.

7 MR. FINKELSTEIN: For what it's
8 worth, the witness said 823, not E 23.

9 QUESTIONS BY MS. SINGER:

10 Q. Now, you were asked in the
11 first two days of your deposition some
12 questions about whether DEA implicitly or
13 explicitly approved of distributors'
14 compliance programs.

15 Do you remember that line of
16 questioning?

17 A. Yes.

18 Q. Okay. And you testified that
19 if the DEA found problems, like not reporting
20 suspicious orders, you would let the
21 registrant know they needed to make
22 adjustments; is that correct?

23 A. Now, I don't understand that
24 that's the totality of what I stated.

25 Q. Okay. So --

1 MR. EPPICH: Well, let me
2 object to it misstates prior
3 testimony, please.

4 QUESTIONS BY MS. SINGER:

5 Q. Okay. So would the DEA let a
6 registrant know if it was aware of problems
7 with its suspicious order monitoring system?

8 MS. MAINIGI: Objection.
9 Vague. Form. Foundation.

10 MR. FINKELSTEIN: Incomplete
11 hypothetical.

12 MS. MAINIGI: And time period.

13 THE WITNESS: So how I would
14 respond to this particular question is
15 when we sit down with a registrant and
16 they're explaining their system to us,
17 we are in a listening mode. We are
18 listening to what they say: "This is
19 what we're going to do. This is how
20 we're going to implement it. These
21 are the thresholds. These are the" --
22 whatever. They're explaining the
23 system to us, so we listen to what
24 they're saying.

25 If we, in listening to that,

1 they ask -- or we hear something that
2 doesn't sound quite right, we would
3 offer and say, "Well, you might want
4 to look at this."

5 Sort of exactly like the
6 Rannazzisi letters in which we laid
7 out the foundation of these are the
8 things that we're seeing. We're
9 having trouble trying to figure out
10 why this is going on. So we're asking
11 you to ask the same questions of
12 yourselves of the data that you're
13 seeing.

14 So what we're trying to do is
15 we're trying to put people in
16 compliance so that this stops, that
17 the diversion stops. So, yes, we
18 would -- we would offer suggestions to
19 them.

20 However, if we're into an
21 investigation or something where it --
22 where we are either investigating or
23 litigating, that might -- that
24 conversation might slow down.
25

1 QUESTIONS BY MS. SINGER:

2 Q. Understood.

3 And the fact that DEA doesn't
4 alert a registrant to a problem with their
5 suspicious order monitoring program doesn't
6 mean the problem doesn't exist, does it?

7 MR. EPPICH: Object to form.
8 Calls for speculation. Calls for a
9 legal conclusion.

10 MS. FUMERTON: And lack of
11 foundation.

12 THE WITNESS: Yes.

13 QUESTIONS BY MS. SINGER:

14 Q. Yes. Okay.

15 So, for instance, if I turn in
16 my taxes and the IRS cashes the check and
17 doesn't send me an audit letter, it doesn't
18 mean that they've approved of a tax shelter
19 that I may have?

20 MR. EPPICH: Objection.
21 Incomplete hypothetical form.

22 QUESTIONS BY MS. SINGER:

23 Q. Not that I do.

24 MR. EPPICH: Objection. Form.
25 Incomplete hypothetical.

1 MS. FUMERTON: Outside the
2 scope.

3 MR. FINKELSTEIN: Scope.
4 Unless you're talking about my taxes.

5 THE WITNESS: Yes.

6 QUESTIONS BY MS. SINGER:

7 Q. Okay. So you testified, too,
8 that things can look good on paper or look
9 fine on paper, but what matters is how they
10 work in practice, correct?

11 MR. EPPICH: Objection to the
12 extent it misstates prior testimony.

13 THE WITNESS: Well, the
14 regulations require two things:
15 design and operate. So the design
16 would be this is what we propose, this
17 is what our system looks like, and
18 then becomes, well, what, in fact, did
19 you do with the operation of it.

20 QUESTIONS BY MS. SINGER:

21 Q. Okay. And you, the DEA, can't
22 always see what distributors don't do or do
23 wrong, especially if they're trying not to be
24 caught, correct?

25 MR. EPPICH: Object to the

1 form. Foundation.

2 MS. MAINIGI: Incomplete

3 hypothetical and outside the scope.

4 THE WITNESS: Correct.

5 (Prevoznik Plaintiff's Exhibit

6 P42 marked for identification.)

7 QUESTIONS BY MS. SINGER:

8 Q. Okay. I want to turn to

9 Exhibit 42.

10 It is Exhibit Number 7 to the

11 Boggs deposition. It's called "American

12 Pain: The Largest US Pill Mill's Rise and

13 Fall."

14 Have you seen this article

15 before?

16 A. I don't -- I don't know of this

17 one in particular. I've seen a lot of

18 articles.

19 Q. Okay. And I want you to turn

20 to the -- I don't know if it's tabbed on your

21 copy, but page -- the page that starts

22 "Harvard Drug" on the top. I think it's the

23 fifth page.

24 Do you see that page?

25 A. Yes.

1 Q. And if you go down towards the
2 bottom of the page, there's a paragraph that
3 begins with "Gary Boggs, special agent with
4 the DEA's Office of Diversion Control."

5 Do you see where I am?

6 A. Yes.

7 Q. And do you know who Gary Boggs
8 is?

9 A. Yes.

10 Q. And who is Gary Boggs?

11 A. He was one of the assistants to
12 Joe Rannazzisi when Joe was the head of the
13 diversion program.

14 Q. Okay. And this article, if you
15 look at page 1, is dated 2012.

16 Do you know if Gary Boggs was
17 with DEA in 2012?

18 Or it identifies him here as a
19 special agent with DEA's Office of Diversion
20 Control.

21 A. Yeah, I'm just trying to think,
22 because I got to headquarters in 2012, so he
23 was there for part of it, but I think he may
24 have -- not 100 percent, but he may have
25 retired towards the end of the year.

1 Q. Okay. So it says here, "Gary
2 Boggs, special agent with the DEA's Office of
3 Diversion Control, says the cases that the
4 DEA has brought in recent years involved
5 wholesalers knowingly making enormous sales
6 to customers that were per se in violation of
7 DEA's rules."

8 Do you see where I'm reading?

9 A. Yes.

10 Q. And does the DEA agree with
11 that statement?

12 MR. EPPICH: Object to the
13 form. Foundation. Scope.

14 THE WITNESS: Yes.

15 QUESTIONS BY MS. SINGER:

16 Q. And then it goes on quoting
17 Mr. Boggs, "The notion put out by HDMA that
18 somehow or another the DEA is not providing
19 essential information to them is simply not
20 accurate, says Boggs. It's a smokescreen.
21 It's a step out of desperation."

22 Do you see that statement?

23 A. Yes.

24 Q. Okay. Do you agree with that
25 statement?

1 MR. EPPICH: Objection to the
2 form. Scope. Foundation.

3 MR. FINKELSTEIN: Object to the
4 form.

5 THE WITNESS: Yes.

6 (Prevoznik Plaintiff's Exhibit
7 P43 marked for identification.)

8 QUESTIONS BY MS. SINGER:

9 Q. All right. Moving to the next
10 exhibit.

11 By the way, do you know what
12 Gary Boggs does now?

13 MR. EPPICH: Objection to form.
14 Calls for speculation.

15 THE WITNESS: He works for
16 McKesson.

17 QUESTIONS BY MS. SINGER:

18 Q. All right. Exhibit 43,
19 Mr. Prevoznik.

20 This is MCKMDL00661483.

21 MR. FINKELSTEIN: Can I get
22 another copy of this, please?

23 QUESTIONS BY MS. SINGER:

24 Q. All right. And this is an
25 e-mail Re: Report on House Energy and

1 Commerce Subcommittee Hearing on DEA and FDA
2 Transparency.

3 And I'll direct you to the
4 middle of the e-mail from Ann Berkey.

5 Do you see where I am?

6 A. Yes.

7 Q. Okay. And it's dated Tuesday,
8 April 8, 2014.

9 And if you look in the text of
10 that e-mail, it says, "I met today with Gary
11 Boggs, the new senior director of reg affairs
12 for US pharma for the east of the Mississippi
13 River, that is, who is based in Livonia.
14 He's a former top official with the DEA, and
15 we talked extensively about this bill, the
16 hearing, ways we can work with the Agency, et
17 cetera. He outlined in some detail the
18 processes that the DEA has had in place for
19 years to, quote, collaborate with wholesalers
20 in the way in which our industry, CAH" --

21 Do you know what CAH refers to?

22 MR. EPPICH: Objection.

23 Foundation. Calls for speculation.

24 THE WITNESS: No, I don't.

25

1 QUESTIONS BY MS. SINGER:

2 Q. Do you know if that might be
3 Cardinal Health?

4 A. It could be.

5 MR. EPPICH: Objection.
6 Foundation.

7 MS. MAINIGI: Outside the
8 scope.

9 MR. EPPICH: Asked and
10 answered.

11 MS. MAINIGI: Ms. Singer, we
12 would appreciate it if you were not
13 testifying.

14 MS. SINGER: I don't think I
15 was.

16 QUESTIONS BY MS. SINGER:

17 Q. -- "has blown them off to the
18 point that the DEA is now hammering all of
19 us."

20 Does this accurately reflect
21 the sense of the -- is it true that the DEA
22 felt that the industry did not respond to
23 their guidance and request for compliance?

24 MR. MAHADY: Objection. Form.
25 Objection. Foundation.

1 MS. MAINIGI: Outside the
2 scope.

3 MR. EPPICH: Objection. Form.
4 Calls for speculation. No foundation.

5 MR. FINKELSTEIN: Vague as to
6 time.

7 THE WITNESS: Yes.

8 QUESTIONS BY MS. SINGER:

9 Q. And this is as of 2014,
10 correct?

11 MR. EPPICH: Objection.
12 Foundation. Misstates the document.
13 Form.

14 THE WITNESS: Yes, that's the
15 date on the e-mail.

16 QUESTIONS BY MS. SINGER:

17 Q. All right. Turn to the next
18 page, please. It says, towards the top, "Per
19 our discussion with Rep Burgess."

20 Do you see where I am?

21 A. Yes.

22 Q. "Per our discussion with Rep
23 Burgess on Saturday, his office called me
24 this afternoon before the hearing and asked
25 me for questions he could ask DEA." Stop

1 there.

2 Now, do you know who Ann Berkey
3 is?

4 MR. EPPICH: Objection. Calls
5 for speculation.

6 QUESTIONS BY MS. SINGER:

7 Q. No?

8 A. No.

9 Q. Okay. Were you aware that the
10 HDA was providing questions to members of
11 Congress, or Representative Burgess in
12 particular, to ask DEA at an upcoming
13 hearing?

14 MR. EPPICH: Objection.
15 Foundation. Scope. Form.

16 MR. FINKELSTEIN: I'll join the
17 scope objection.

18 THE WITNESS: Me personally,
19 no, I did not know that.

20 (Prevoznik Plaintiff's Exhibit
21 P44 marked for identification.)

22 QUESTIONS BY MS. SINGER:

23 Q. Okay. Next exhibit.

24 Okay. Exhibit 44. This is
25 ABDCMDL00139028.

1 It's called Summary of DEA HDMA
2 meeting, December 19, 2011.

3 Do you recall a meeting between
4 the DEA and HDMA in 2011?

5 MR. EPPICH: Objection.
6 Foundation.

7 THE WITNESS: I don't.

8 QUESTIONS BY MS. SINGER:

9 Q. The DEA did meet with the HDMA
10 periodically, correct?

11 MR. EPPICH: Objection.
12 Foundation.

13 THE WITNESS: Correct.

14 QUESTIONS BY MS. SINGER:

15 Q. Okay. And down at the bottom
16 of the page here, in the last paragraph, it
17 says, "HDMA asked if there was any -- if
18 there were any noncompliance trends
19 throughout the wholesale distribution
20 industry we should inform our members about."

21 Do you see where I am?

22 A. Yes.

23 Q. Okay. "Gary Boggs" --

24 Who we talked about just a
25 minute ago, correct?

1 A. Yes.

2 MR. EPPICH: Objection.

3 QUESTIONS BY MS. SINGER:

4 Q. -- "the executive assistant to
5 the deputy administrator for diversion
6 control, led this response. He stated that
7 DEA's single greatest concern was their
8 belief that wholesaler distributors were lax
9 in analysis, review and acting on their own
10 ARCOS data. He stated that sometimes the
11 data were pretty egregious. He went on to
12 explain," turning the page, "that the Agency
13 had not seen changes in registrants' behavior
14 that it expected after presenting its
15 analysis of ARCOS data to them, so we have --
16 quote, 'so we have upped our game.'"

17 Is this consistent with the
18 DEA's view and your testimony that
19 registrants were lax in their analysis,
20 review and acting on their own ARCOS data?

21 MR. EPPICH: Object to form.

22 Misstates testimony. Foundation.

23 THE WITNESS: Yes.

24 QUESTIONS BY MS. SINGER:

25 Q. And was it pretty egregious?

1 MR. EPPICH: Objection to form.

2 Foundation.

3 MS. MAINIGI: Vague.

4 THE WITNESS: Yes.

5 QUESTIONS BY MS. SINGER:

6 Q. And when it says here that DEA
7 had "upped its game," do you know what that's
8 referring to?

9 MR. EPPICH: Objection to form.

10 Foundation.

11 MS. MAINIGI: Outside scope.

12 THE WITNESS: At this time
13 period, we were investigating and
14 litigating against the wholesalers.

15 QUESTIONS BY MS. SINGER:

16 Q. Okay. Prompted by DEA's sense
17 that that's what they needed to do given a
18 lack of voluntarily compliance, correct?

19 MR. EPPICH: Object to the
20 form. Misstates testimony.

21 Foundation.

22 THE WITNESS: Yes.

23 (Prevoznik Plaintiff's Exhibit
24 P45 marked for identification.)
25

1 QUESTIONS BY MS. SINGER:

2 Q. Exhibit 45. This is
3 CAH_MDL2804_01530082. And I'll represent
4 that this is an HDMA document.

5 And I'd like to direct you to
6 page 2. I'm sorry, not page 2, page 1,
7 number 2. Just throwing you for a loop.

8 Do you see the row that
9 indicates "Petition DEA for a regulation to
10 clarify suspicious orders and/or suspicious
11 order monitoring expectations"?

12 Do you see where I am?

13 A. Yes.

14 Q. Okay. And it says in the far
15 right column, "Favored this option above all
16 the others. Unlikely that DEA would create
17 such a regulation; therefore, low risk of
18 resulting in something overly restrictive or
19 difficult to follow. A good ask. The optics
20 would be positive. We go on the record as
21 asking for clarity. Recognize that this may
22 be -- this may tie into what is done on the
23 Hill or in a PR campaign, as external
24 pressure may be desirable and/or a legislator
25 may use it as the basis of a new bill. Some

1 went so far as to state we should do this.
2 Urged HDMA to carefully articulate, one, what
3 we believe DEA should address; and two, DEA
4 should only inspect/enforce against what is
5 specified in the regulations."

6 Have I just read that
7 accurately, Mr. Prevoznik?

8 A. Yes.

9 Q. And was DEA aware that the
10 reason HDMA was pressing for clarification of
11 suspicious order and suspicious order
12 monitoring expectations was for the optics of
13 it?

14 MR. EPPICH: Object to form.
15 Foundation. Calls for speculation.

16 MS. MAINIGI: And outside
17 scope.

18 THE WITNESS: No.

19 QUESTIONS BY MS. SINGER:

20 Q. Or that they recognized that it
21 was unlikely that DEA would actually create
22 such a regulation?

23 MR. EPPICH: Object to form.
24 Foundation. Scope.

25 MS. MAINIGI: Misstates the

1 document, and it's outside the scope
2 of the Touhy authorization.

3 THE WITNESS: Can you repeat
4 that, please?

5 QUESTIONS BY MS. SINGER:

6 Q. Or that they recognized that it
7 was unlikely that DEA would create such a
8 regulation, so it was a low risk for
9 industry?

10 MS. MAINIGI: Same objections.

11 THE WITNESS: Correct.

12 QUESTIONS BY MS. SINGER:

13 Q. When you were testifying -- and
14 you can put that away, Mr. Prevoznik.

15 When you were testifying
16 earlier in your deposition --

17 MR. BENNETT: If I might
18 interrupt for one second, I believe
19 there was -- in the record you asked
20 the question, and I think the witness
21 said "correct," and it was transcribed
22 as "no." But I just want the record
23 to be clear what your answer was to
24 her last question.

25 THE WITNESS: I believe it was

1 "correct."

2 MS. SINGER: Thank you.

3 QUESTIONS BY MS. SINGER:

4 Q. All right. In your testimony
5 on day one or day two, you were asked whether
6 suspicious orders always lead to diversion.

7 Do you remember?

8 A. Yes.

9 MS. MAINIGI: Objection to
10 form. Vague.

11 QUESTIONS BY MS. SINGER:

12 Q. Okay. And I think your answer
13 to that was, no, it doesn't always lead to
14 diversion.

15 Does that seem right to you?

16 MR. EPPICH: Objection. The
17 transcript speaks for itself.

18 THE WITNESS: Yes.

19 QUESTIONS BY MS. SINGER:

20 Q. Okay. And is that because,
21 Mr. Prevoznik, not all suspicious orders turn
22 out to actually be suspicious?

23 A. Correct.

24 MR. EPPICH: Objection to form.

25

1 QUESTIONS BY MS. SINGER:

2 Q. Okay. But if a distributor
3 doesn't investigate a suspicious order, it
4 wouldn't know whether that order was being
5 diverted, right?

6 MR. EPPICH: Object to the
7 form. Calls for speculation.

8 THE WITNESS: Yes.

9 QUESTIONS BY MS. SINGER:

10 Q. And to use the language we
11 quoted earlier from the Diversion
12 Investigators Manual, sending out potentially
13 suspicious orders without investigating them
14 reflects a, quote, attitude of
15 irresponsibility.

16 Does DEA agree?

17 MS. MAINIGI: Objection to
18 form. Outside the scope. Vague.

19 THE WITNESS: Yes.

20 (Prevoznik Plaintiff's Exhibit
21 P46 marked for identification.)

22 QUESTIONS BY MS. SINGER:

23 Q. Let's turn to the Energy and
24 Commerce. Since we don't have previous --
25 the exhibits from last time, we're going to

1 remark the Energy and Commerce report as
2 Exhibit 46. It's the same report that went
3 in earlier in your testimony.

4 And industry lawyers asked
5 you -- they showed you a piece of the report
6 that said that DEA could have acted earlier.

7 Do you remember those
8 questions?

9 A. Vaguely, but, yes.

10 Q. Okay. And certainly this
11 Energy and Commerce report finds the DEA
12 could have done more than it did, correct?

13 A. Correct.

14 Q. Okay. But it's also highly
15 critical of distributors, is it not?

16 MR. EPPICH: Objection.

17 MS. MAINIGI: Objection.

18 Foundation. Outside the scope.

19 MR. FINKELSTEIN: Join the
20 scope objection.

21 THE WITNESS: Yes.

22 QUESTIONS BY MS. SINGER:

23 Q. Okay. And just for context, I
24 want to direct you to page 5 of the report.

25 On the bottom of the page, it

1 says in that last paragraph, "As the opioid
2 epidemic began to surge, the DEA, by 2005,
3 realized that traditional policing of
4 individual doctors and pharmacies was no
5 longer an effective approach against the
6 oncoming avalanche of opioids from rogue
7 Internet pharmacies and pill mills. Instead,
8 DEA's focus turned to the drug wholesale
9 distributors, a choke point in the
10 pharmaceutical supply chain, who transfer
11 drugs from manufacturers to businesses such
12 as clinics, hospitals and pharmacies where
13 they can be dispensed to patients.
14 Distributors in previous years had not
15 received enforcement attention from the DEA.
16 The new focus looked for greater impact for
17 the highly consolidated industry given the
18 three -- given that the three major drug
19 distributors - AmerisourceBergen, Cardinal
20 Health and McKesson - control about
21 85 percent of the drug supply."

22 Do you agree with the statement
23 I've just read?

24 A. Yes.

25 MS. MAINIGI: Objection.

1 QUESTIONS BY MS. SINGER:

2 Q. And then "Beginning in 2005,
3 the DEA undertook a series of initiatives
4 meant to educate wholesale drug distributors
5 about their legal obligations to prevent
6 controlled substance diversion. The DEA's
7 distributor initiative included one-on-one
8 meetings with wholesale distributors in which
9 DEA officials provided specific examples
10 regarding distributors' own customers whose
11 ordering habits were suggestive of trends
12 indicating the presence of diversion and
13 illicit Internet pharmacies. Of the five
14 distributors investigated by the committee,
15 AmerisourceBergen, Cardinal, HD Smith and
16 McKesson, each had one-on-one meetings with
17 DEA as part of this initiative. In addition,
18 during 2006 and 2007, the DEA sent a series
19 of three letters, sent to all DEA-registered
20 distributors outlining their legal
21 obligations to conduct due diligence and
22 report suspicious orders."

23 Is that also an accurate
24 statement of what happened?

25 MR. EPPICH: Object to form.

1 Foundation. Calls for speculation.

2 THE WITNESS: Yes.

3 QUESTIONS BY MS. SINGER:

4 Q. "Apparently the DEA soon
5 realized that the largest distributors were
6 not taking their compliance requirements with
7 sufficient seriousness. In 2007 and 2008,
8 the DEA took enforcement action through legal
9 settlements against the three largest
10 wholesale distributors in the US for alleged
11 violations of the CSA, with multi-million
12 dollar fines involving two of them."

13 Is that also accurate?

14 MR. EPPICH: Object to form.

15 MS. MAINIGI: Objection to
16 form.

17 THE WITNESS: Yes.

18 QUESTIONS BY MS. SINGER:

19 Q. Last paragraph. "Despite these
20 settlement agreements and the subsequent
21 policy enhancements that the three
22 distributors made in their aftermath, the
23 committee found that the distributors
24 continued to ship large volumes of opioids
25 into West Virginia. The three largest

1 wholesale drug distributors in the United
2 States - AmerisourceBergen, Cardinal Health
3 and McKesson - sent more than 900 million
4 doses of hydrocodone and oxycodone to West
5 Virginia between 2005 and 2016. Cardinal
6 Health was the largest supplier of controlled
7 substances to West Virginia out of the five
8 companies examined as part of the Committee's
9 investigation, and distributed more than 366
10 million doses of hydrocodone and oxycodone to
11 West Virginia pharmacies between 2005 and
12 2016. From April 2006 through 2016, McKesson
13 supplied 299.87 million doses of hydrocodone
14 and oxycodone to West Virginia pharmacies,
15 AmerisourceBergen distributed 248.16 million
16 doses of hydrocodone and oxycodone to West
17 Virginia pharmacies between 2005 and 2016."

18 Is that also consistent with
19 DEA's understanding of what had occurred?

20 MR. EPPICH: Object to the
21 form. Foundation.

22 THE WITNESS: Yes.

23 QUESTIONS BY MS. SINGER:

24 Q. Turn the page, please. "Among
25 the Committee's findings, distributors

1 suffered a series of breakdowns or had a lack
2 of follow-through in their -- through in
3 their due diligence evaluations of
4 prospective pharmacy customers. As
5 demonstrated in the report, the committee
6 found instances of insufficient due diligence
7 by distributors who merely required
8 pharmacies to complete new customer
9 applications."

10 Now, we talked about that
11 earlier, correct?

12 MR. EPPICH: Object to the
13 form.

14 THE WITNESS: Correct.

15 QUESTIONS BY MS. SINGER:

16 Q. And that is not sufficient to
17 comply with the registrant's obligation to
18 know their customers, correct?

19 MR. EPPICH: Object to the
20 form. Foundation.

21 MS. MAINIGI: Calls for a legal
22 conclusion.

23 THE WITNESS: Correct.

24 QUESTIONS BY MS. SINGER:

25 Q. "There were cases where data

1 submitted by a new customer was not
2 critically analyzed to identify any red flags
3 of controlled substance diversion, for
4 example, potential red flags regarding a
5 pharmacy's prescribing physicians that raised
6 concerns about possible diversion were not
7 questioned."

8 Is that consistent with DEA's
9 understanding of what occurred?

10 MR. EPPICH: Object to form.
11 Foundation.

12 THE WITNESS: Yes.

13 QUESTIONS BY MS. SINGER:

14 Q. Goes on to say, "The
15 investigation found instances where there
16 were failures to monitor the volume of
17 controlled substances sold to customers.
18 Some distributors used thresholds to track
19 customers' purchases of controlled substances
20 and flag orders as suspicious when purchases
21 exceeded those limits. But some of these
22 thresholds were assigned arbitrarily and not
23 effective. Committee found instances in
24 which distributors set thresholds but failed
25 to enforce them, assigned artificially high

1 hydrocodone threshold limits with little to
2 no documented justification, or continued to
3 raise threshold levels without thoroughly
4 investigating or documenting the
5 justifications presented by a customer
6 pharmacy."

7 Again, is that what DEA
8 observed happened during this time period?

9 MR. EPPICH: Object to the
10 form. Foundation. Calls for
11 speculation.

12 MS. MAINIGI: Join.

13 THE WITNESS: Yes.

14 QUESTIONS BY MS. SINGER:

15 Q. Okay. And is that failure to
16 flag suspicious orders, to approve them
17 without justification and to continue to
18 raise thresholds, a violation of the
19 Controlled Substances Act?

20 MS. MAINIGI: Objection. Calls
21 for a legal conclusion. Outside the
22 scope.

23 MR. EPPICH: Objection to the
24 form.

25 MR. FINKELSTEIN: Object to

1 form.

2 THE WITNESS: Yes.

3 QUESTIONS BY MS. SINGER:

4 Q. It goes on, "Despite efforts by
5 DEA to educate distributors about their
6 responsibility to report suspicious orders,
7 the companies reviewed by the committee
8 failed to address suspicious orders" -- I'm
9 sorry -- "suspicious order monitoring in
10 critical ways. Rather than reporting
11 individual suspicious orders as they were
12 identified, some distributors reported a
13 variety of other types of information to DEA
14 over the years. This information included
15 excessive orders encompassing drug shipments
16 that had already been shipped and suspicious
17 customers such as pharmacies with which
18 distributors had terminated business
19 relationships. Neither of these types of
20 reports informed DEA about suspicious orders
21 in realtime, nor did they guarantee the
22 suspicious orders reported to DEA were also
23 blocked by the distributors. The committee
24 also found that one distributor lacked any
25 formal order monitoring program. Rather, the

1 distributor's employees relied on subjective
2 criteria to investigate {sic} orders it
3 considered suspicious."

4 Does that also reflect what the
5 DEA knew to happen during this time period?

6 MS. MAINIGI: Objection. Form.
7 Foundation. Outside scope.

8 MR. FINKELSTEIN: Object to the
9 form.

10 THE WITNESS: Yes.

11 QUESTIONS BY MS. SINGER:

12 Q. And the last paragraph.
13 "Another critical failure identified by the
14 Committee involved instances in which
15 distributors appeared to turn a blind eye to
16 red flags of possible drug diversion.
17 Despite available information, distributors
18 at times took only minimal steps to
19 investigate possible warning signs of
20 diversion and continued to ship controlled
21 substances to suspect pharmacies. In several
22 cases, distributors either failed to fully
23 investigate potentially troubling information
24 they obtained from customer pharmacies or
25 willfully ignored it. These failures raise

1 substantial concern given that DEA has said
2 existing knowledge of a geographic area's
3 problem with controlled substance abuse is a
4 factor that distributors should take into
5 account when evaluating customers."

6 Now, is that true, that DEA had
7 said knowledge of a geographic area's problem
8 with controlled substance abuse is a factor
9 that should be taken into account by
10 registrants?

11 MR. EPPICH: Object to the
12 form.

13 MS. MAINIGI: Object to form.

14 THE WITNESS: Yes.

15 QUESTIONS BY MS. SINGER:

16 Q. Okay. "West Virginia has the
17 highest drug overdose rate in the country,
18 meaning distributors should have been
19 particularly attuned to any red flags
20 encountered when conducting due diligence on
21 pharmacies in that state."

22 Is that also an accurate
23 reflection of a registrant's duty when
24 shipping controlled substances into West
25 Virginia or other hotspots?

1 MR. EPPICH: Object to form.

2 Calls for a legal conclusion.

3 MS. MAINIGI: Outside the
4 scope.

5 THE WITNESS: Yes.

6 QUESTIONS BY MS. SINGER:

7 Q. Okay. And this whole paragraph
8 that I just read, does that also reflect the
9 DEA's understanding of what happened during
10 this time period?

11 MR. EPPICH: Object to the
12 form. Vague. Calls for a legal
13 conclusion.

14 MR. FINKELSTEIN: Join in the
15 form objection.

16 THE WITNESS: Yes.

17 QUESTIONS BY MS. SINGER:

18 Q. Okay. Turn to page 10, please.
19 Bottom of page 10 there's a bullet that says,
20 "For due process reasons, it is current DEA
21 practice not to inform distributors or other
22 registrants about customers that may have
23 engaged in improper behavior."

24 Do you see where I am?

25 A. The bottom?

1 Q. Yes.

2 A. Yes.

3 Q. And does that accurately
4 reflect DEA's policy?

5 MR. EPPICH: Objection to form.

6 MR. FINKELSTEIN: Hang on. We
7 had a different witness to testify
8 about this. You declined to ask her
9 questions. I'm going to instruct him
10 not to answer now.

11 MS. SINGER: Okay.

12 QUESTIONS BY MS. SINGER:

13 Q. So turning to page 16.

14 And I want to be respectful of
15 the scope of your authorization and not ask
16 you about individual investigations or
17 current matters. But to the extent you can
18 testify consistent with your authorization, I
19 want to point you to the third bullet:

20 "McKesson supplied just under 300 million
21 doses of hydrocodone and oxycodone to West
22 Virginia pharmacies between April 2006 and
23 2016."

24 Is that accurate?

25 MR. EPPICH: Object to the

1 form. Foundation. Calls for
2 speculation.

3 MS. MAINIGI: Outside scope.

4 MR. EPPICH: May be outside the
5 Touhy authorization as well.

6 MS. MAINIGI: That's what I
7 meant.

8 THE WITNESS: I mean, I don't
9 have the data in front of me to
10 confirm those numbers.

11 QUESTIONS BY MS. SINGER:

12 Q. Okay. What about the next
13 bullet: "McKesson did not submit suspicious
14 order reports to the DEA regarding orders
15 placed by West Virginia pharmacies until
16 August 1, 2013."

17 Do you know whether that's
18 accurate?

19 MR. EPPICH: Object to form.
20 Foundation. Calls for speculation.
21 Outside the Touhy authorization.

22 MR. FINKELSTEIN: This is
23 outside the Touhy authorization to the
24 extent that it calls for information
25 about West Virginia specifically.

1 MS. MAINIGI: The entire report
2 calls for information that relates to
3 West Virginia.

4 MR. FINKELSTEIN: And our
5 authorization to the plaintiffs was --
6 concluded investigations and
7 settlements with the defendants, but
8 we specifically didn't authorize
9 region-specific investigations.

10 MS. SINGER: Okay. We will
11 skip this then.

12 QUESTIONS BY MS. SINGER:

13 Q. Okay. Let's turn to page 319.
14 You with me? You at page 319?

15 A. Uh-huh.

16 Q. Okay. Turning towards the
17 middle of the page, just below it, the second
18 paragraph from the bottom. "But as
19 demonstrated by the Committee's
20 investigation, the DEA did not always receive
21 the level of compliance required under the
22 CSA. The five distributors whose actions in
23 West Virginia were examined by the Committee
24 each had unique failures. The companies had
25 various policies and procedures in place to

1 prevent diversion but in some cases did not
2 adequately follow or carry out those
3 policies. As evidenced in the case studies
4 discussed in each section, distributors had
5 failings on multiple fronts."

6 Is that consistent with the
7 DEA's conclusions?

8 MR. EPPICH: Object to the
9 form. Foundation. Calls for
10 speculation. Outside the Touhy
11 authorization.

12 THE WITNESS: Yes.

13 QUESTIONS BY MS. SINGER:

14 Q. "For instance, it is not
15 sufficient due diligence for a distributor to
16 only require prospective or existing
17 customers to complete pharmacy questionnaires
18 or supply supplemental data. The information
19 disclosed on such questionnaires or the data
20 submitted must also be critically analyzed to
21 identify any red flags of controlled
22 substance diversion."

23 Does that accurately reflect a
24 distributor's obligations or a registrant's
25 obligations?

1 MR. EPPICH: Object to the
2 form.

3 THE WITNESS: Yes.

4 QUESTIONS BY MS. SINGER:

5 Q. "Once distributors bring
6 pharmacies on board, they need to monitor the
7 volume of controlled substances sold to
8 customers."

9 Does that also accurately
10 reflect a registrant's duties?

11 MR. EPPICH: Object to form.

12 Calls for a legal conclusion.

13 THE WITNESS: Yes.

14 QUESTIONS BY MS. SINGER:

15 Q. And the last sentence,
16 "Subsequently, when distributors set
17 thresholds for customers, they should be
18 enforced. In such cases where thresholds are
19 adjusted, distributors should be able to
20 document the justification for these
21 changes."

22 Does that also accurately
23 reflect a registrant's obligations?

24 MR. EPPICH: Object to the

25 form. Calls for a legal conclusion.

1 MS. MAINIGI: Vague as to time.

2 THE WITNESS: Yes.

3 QUESTIONS BY MS. SINGER:

4 Q. All right. We can leave this
5 report.

6 Okay. In questioning during
7 the first two days of your deposition,
8 Mr. Prevoznik, do you remember discussing the
9 fact that a small percentage of doctors are
10 engaged in unlawful prescribing?

11 I think it was .5 percent.

12 Do you remember that
13 conversation?

14 A. Yes.

15 (Prevoznik Plaintiff's Exhibit
16 P47 marked for identification.)

17 QUESTIONS BY MS. SINGER:

18 Q. Okay. So I want to turn to
19 Exhibit 47, please.

20 And that is Bates number
21 PPLP0300001799742.

22 If you turn to the first slide,
23 it's titled "DEA/OD 11th Pharmaceutical
24 Industry Conference."

25 Do you recognize this

1 presentation?

2 A. Do we know what year?

3 Q. And what is it?

4 A. No, I said, "Do we know what
5 year?"

6 Q. Oh. So it's Tuesday,
7 September 16th. And if you look at the
8 calendar in the years that are referenced, we
9 believe it to be 2003 because of when
10 Tuesday -- when September 16th is a Tuesday.

11 MR. EPPICH: Objection.

12 THE WITNESS: I've never seen
13 this before.

14 QUESTIONS BY MS. SINGER:

15 Q. Okay. It does have on the
16 front page DOJ, DEA logos, correct?

17 A. Yes.

18 Q. Okay. And does it look -- from
19 your knowledge, is this a presentation by the
20 DEA?

21 MR. EPPICH: Objection.

22 Foundation. Form.

23 THE WITNESS: Yes.

24 QUESTIONS BY MS. SINGER:

25 Q. Okay. And if you turn to the

1 fifth page, with the slide "retail
2 diversion," 90 percent at doctor, pharmacy,
3 hospital levels.

4 Do you see that slide?

5 A. Yes.

6 Q. Okay. And if you look at the
7 notes that are at the bottom of that slide,
8 do you see the bottom section that starts,
9 "Estimated 1.5 percent of doctors are
10 negligent and/or dishonest"?

11 Do you see where I'm reading?

12 A. Yes.

13 Q. Okay. It says, "That portion
14 of DEA-registered physicians is many
15 thousands. Their CS, or controlled
16 substance, prescribing would total hundreds
17 of thousands of scripts/millions of dosage
18 units into illicit market."

19 Is that accurate?

20 MR. EPPICH: Objection.

21 Foundation. Form. Misstates the
22 document. Calls for speculation.

23 MR. FINKELSTEIN: Object to the
24 scope.

25 THE WITNESS: Yes.

1 QUESTIONS BY MS. SINGER:

2 Q. And is it true, as it says
3 here, that it is impossible for DEA to
4 investigate and discipline that number of
5 professionals?

6 MR. EPPICH: Object to form.
7 Foundation.

8 MS. MAINIGI: Scope.

9 THE WITNESS: I mean, we do the
10 best we can.

11 QUESTIONS BY MS. SINGER:

12 Q. But that's a lot of --

13 A. It's a lot.

14 MR. EPPICH: Object to the
15 form.

16 QUESTIONS BY MS. SINGER:

17 Q. And the last line here, "Far
18 more effective, address the risk at the apex
19 of the distribution center {sic}."

20 Is that accurate, that that is
21 a more effective way of enforcing compliance
22 with the Controlled Substances Act?

23 MR. EPPICH: Object to form.
24 Foundation.

25

1 QUESTIONS BY MS. SINGER:

2 Q. Or an important tool for the
3 DEA?

4 MR. EPPICH: Object to form and
5 foundation.

6 THE WITNESS: Yes.

7 QUESTIONS BY MS. SINGER:

8 Q. Okay. And in fact, that's part
9 of the foundation of the Controlled
10 Substances Act, that each participant in the
11 supply chain has to police its own
12 participation in that supply chain, correct?

13 MR. EPPICH: Object to form.
14 Calls for a legal conclusion.
15 Misstates.

16 THE WITNESS: Yes.

17 QUESTIONS BY MS. SINGER:

18 Q. All right. And during the
19 questioning by some of the industry counsel
20 during the first two days of depositions, do
21 you remember the suggestion that prescribers
22 were better situated to identify improper
23 prescriptions?

24 Do you remember that testimony?

25 MR. EPPICH: Objection to form

1 to the extent it misstates prior
2 testimony.

3 THE WITNESS: Not really.

4 (Prevoznik Plaintiff's Exhibit
5 P48 marked for identification.)

6 QUESTIONS BY MS. SINGER:

7 Q. Okay. Is it -- let's just turn
8 to the document.

9 All right. I'm showing you
10 Exhibit 48. And the level -- and I'm sorry,
11 this is CAH_MDL2804_00889528.

12 Do you recognize the logo on
13 the front of this presentation?

14 A. Yes.

15 Q. And what is it?

16 A. It's our Chief Counsel's logo.

17 Q. Okay. And if you turn to the
18 inside first page, How to Keep Or Lose Your
19 DEA Registration, do you recognize this
20 presentation?

21 A. Yes.

22 Q. And what do you recognize it to
23 be?

24 A. It was one of the -- it was --
25 it was given at a conference that we held.

1 Q. A conference --

2 A. For the industry.

3 Q. Okay. A conference that DEA
4 had for industry?

5 A. Yes.

6 Q. And do you know who gave this
7 presentation?

8 Do you know if would have been
9 Linden Barber?

10 MR. EPPICH: Objection. Form.
11 Calls for speculation.

12 THE WITNESS: I believe it was
13 Linden that gave this.

14 QUESTIONS BY MS. SINGER:

15 Q. Okay. And Linden Barber was
16 with the Chief Counsel's Office of DEA,
17 correct?

18 A. Yes.

19 Q. Okay. And if you turn to
20 page 4 of the presentation, titled "Effective
21 Controls Against Diversion," the first point
22 there is what, the first bullet point?

23 A. "Good recordkeeping is
24 essential."

25 Q. Do you agree with that

1 statement?

2 A. Yes.

3 Q. In DEA's experience, is the
4 absence of documentation a fairly good
5 indication that something didn't happen in a
6 registrant's compliance program?

7 MR. EPPICH: Object to the
8 form. Calls for a legal conclusion.

9 THE WITNESS: Yes.

10 QUESTIONS BY MS. SINGER:

11 Q. Okay. Turning to page 9, this
12 is what doesn't work, or how to lose your DEA
13 registration.

14 The second bullet point, what
15 does that say?

16 A. "It is not my job to
17 second-guess the doctor."

18 Q. Okay. And that's not an excuse
19 that the DEA will accept from a registrant,
20 correct?

21 MR. EPPICH: Objection to form.
22 Vague.

23 THE WITNESS: Yes.

24 QUESTIONS BY MS. SINGER:

25 Q. And that's because it's a

1 registrant's responsibility to act on
2 information that points to diversion,
3 correct?

4 MR. EPPICH: Object to form.
5 Calls for a legal conclusion.

6 THE WITNESS: Correct.

7 QUESTIONS BY MS. SINGER:

8 Q. And it's not that the
9 registrant is being asked to judge a
10 prescription or a patient, but to look at red
11 flags like the volume or dose or appearance
12 of a practice, et cetera, correct?

13 MR. EPPICH: Object to the
14 form. Calls for a legal conclusion.
15 Vague.

16 THE WITNESS: Yes, they should
17 look into totality of everything
18 that's presented to them.

19 QUESTIONS BY MS. SINGER:

20 Q. Okay. And the last excuse on
21 this slide, "I'm not responsible for what my
22 customer does with the drugs."

23 Is that an excuse that the DEA
24 accepts from a registrant?

25 MR. EPPICH: Object to form.

1 Vague.

2 THE WITNESS: No.

3 QUESTIONS BY MS. SINGER:

4 Q. And that's because a registrant
5 is responsible to make sure that they are not
6 supplying to potential diversion, correct?

7 MR. EPPICH: Object to the
8 form. Calls for a legal conclusion.
9 Vague.

10 THE WITNESS: Correct.

11 QUESTIONS BY MS. SINGER:

12 Q. And do you know what Linden
13 Barber does now, by the way?

14 MS. MAINIGI: Objection.
15 Outside the scope.

16 THE WITNESS: I believe -- I
17 believe he's still with Cardinal.

18 QUESTIONS BY MS. SINGER:

19 Q. Now, you were asked by --

20 MR. FINKELSTEIN: Let's take
21 our last break before lunch.

22 MS. SINGER: Okay.

23 VIDEOGRAPHER: We're going off
24 record. The time is 11:36.

25 (Off the record at 11:36 a.m.)

1 VIDEOGRAPHER: We're going back
2 on the record. Beginning of Media
3 File 4. The time is 11:48.

4 QUESTIONS BY MS. SINGER:

5 Q. So, Mr. Prevoznik, just turning
6 back for a minute to the Linden Barber
7 presentation we were talking about before the
8 break, which is Bates number 889528, I want
9 to ask you to turn to page 13, please.

10 And it's a slide titled "How to
11 Keep Your DEA Registration."

12 Do you see that?

13 A. Yes.

14 Q. Okay. And it says in the --
15 under the first master bullet, "Master the
16 obvious: Recordkeeping, reporting," and the
17 last item, "Does it quack like a diverting
18 duck."

19 Is what Mr. Barber is saying
20 here, what the DEA is saying, is if it looks
21 like a suspicious order, it's a suspicious
22 order?

23 A. Yes.

24 Q. And that if it has the signs,
25 quacks like a duck, walks like a duck,

1 whatever that expression is, that it's a
2 duck; it's a suspicious order, correct?

3 MS. MAINIGI: Objection. No
4 foundation. Outside the scope of the
5 Touhy authorization.

6 THE WITNESS: Yes.

7 QUESTIONS BY MS. SINGER:

8 Q. Okay. And then it goes on to
9 say, "Know your customers and, where
10 applicable, the prescriber's business or
11 professional practice."

12 Is that also the DEA's guidance
13 to industry as to what's required?

14 A. Yes.

15 Q. And "know the statutory
16 factors, the DEA's final orders," and then
17 lastly, "act consistently with DEA's goal:
18 protect the public health and safety from the
19 harms caused by diversion."

20 Is that also the guidance that
21 DEA gave to industry about complying with the
22 Controlled Substances Act?

23 A. Yes.

24 MS. MAINIGI: Objection. Form.
25 (Prevoznik Plaintiff's Exhibit

1 P49 marked for identification.)

2 QUESTIONS BY MS. SINGER:

3 Q. Okay. And then I want to turn
4 you to what we'll mark as Bates -- as
5 Exhibit 49.

6 And this is
7 Anda_Opioids_MDL_0000476052. It's "What You
8 Know and Who You Know," a presentation by
9 Linden Barber.

10 Do you see where I'm reading
11 from?

12 A. Yes.

13 Q. And it's dated April 19, 2012,
14 correct?

15 A. Yes.

16 Q. Okay. And at this point Linden
17 Barber is no longer with the DEA, correct?

18 A. Correct.

19 Q. Okay. And it seems that he's
20 with Cegedim.

21 We heard that name before,
22 correct?

23 MS. MAINIGI: Objection.

24 Foundation. Outside the scope of the
25 Touhy authorization.

1 MR. FINKELSTEIN: Scope.

2 You can answer, if you know.

3 THE WITNESS: I'm not sure.

4 QUESTIONS BY MS. SINGER:

5 Q. Okay. I'd like to direct you
6 to page 10 of the presentation, Bates
7 number 6061.

8 And I'm sorry, before you go
9 there, on the title page of the presentation
10 it indicates Linden Barber is the director of
11 DEA compliance operations at Quarles & Brady?

12 A. Yes.

13 Q. Okay. All right. So turning
14 to slide 10, Bates number 6061, it says,
15 "Know Your Regulator."

16 Do you see where I'm reading?

17 A. Yes.

18 Q. "Access to customer due
19 diligence files." And it says under the
20 second bullet, "What is a customer's due
21 diligence file? Not a record required by law
22 to be made or kept. Proof that a
23 distributor -- the distributor is attempting
24 to prevent diversion. Proof that the
25 distributor heeded DEA's warning. Exhibit A

1 in DEA's case against you."

2 Do you understand what

3 Mr. Barber is saying here?

4 MS. MAINIGI: Objection.

5 Foundation. Outside the scope of the

6 Touhy authorization.

7 MR. FINKELSTEIN: Calls for

8 speculation. I agree with the scope

9 objection.

10 MS. SINGER: Okay. Let me --

11 I'm sorry. Let me rephrase it.

12 QUESTIONS BY MS. SINGER:

13 Q. Is it the DEA's position that a

14 customer due diligence file is not required

15 to be made or kept?

16 MS. MAINIGI: Objection. Asked

17 and answered. Objection. Form.

18 QUESTIONS BY MS. SINGER:

19 Q. It's certainly not -- when

20 Mr. Barber was with DEA in that presentation

21 we just looked at, he encouraged

22 recordkeeping, correct, as a way a registrant

23 could keep their DEA license, correct?

24 A. Correct.

25 Q. Okay. And here he's saying not

1 a record required by law to be made or kept,
2 correct?

3 MS. MAINIGI: Objection to
4 form. Objection. Outside the scope
5 of the Touhy authorization. Calls for
6 a legal conclusion.

7 THE WITNESS: What he's saying
8 is that -- I'm speculating on this,
9 but what he's saying, to me, is that
10 the actual terms "due diligence" is
11 not in the regulations; however, I
12 mean, the statute's to prevent -- to
13 have effective means to guard against
14 diversion, you would have to know who
15 your customer is.

16 And so doing that, you would
17 have -- I mean, dealing with as many
18 customers that each of these
19 distributors have, you would have to
20 know who your customers are. So if
21 you don't have files on them, it would
22 be very hard to maintain effective
23 controls.

24 QUESTIONS BY MS. SINGER:

25 Q. Right. Understood.

1 All right. We can leave this
2 document.

3 Now, you were asked during
4 day one or two of your deposition how a
5 manufacturer would know if a prescriber was
6 suspicious.

7 Do you remember those
8 questions?

9 A. Yes.

10 MR. EPPICH: Object to the
11 form.

12 THE WITNESS: Yes.

13 QUESTIONS BY MS. SINGER:

14 Q. Would DEA agree that a
15 significant increase in a prescriber's volume
16 is a sign of potential diversion?

17 MR. EPPICH: Object to the
18 form. Calls for a legal conclusion.

19 THE WITNESS: Just volume
20 alone?

21 QUESTIONS BY MS. SINGER:

22 Q. That it is one sign of
23 potential diversion, yes.

24 A. It --

25 MR. EPPICH: Object to the

1 form.

2 THE WITNESS: Potentially, yes.

3 QUESTIONS BY MS. SINGER:

4 Q. Okay. And that a prescriber
5 who is prescribing at very high volume
6 relative to other practitioners, that would
7 also be another potential red flag of
8 diversion, correct?

9 MR. EPPICH: Object to the
10 form. Form. Vague. Improper
11 hypothetical. Calls for a legal
12 conclusion.

13 THE WITNESS: It could be. It
14 just depends on what is the
15 physician's practice; does he
16 specialize in end of life or something
17 like that. I mean, you'd have to take
18 in other factors.

19 QUESTIONS BY MS. SINGER:

20 Q. Right. You have to look at the
21 whole picture.

22 But that's one sign that might
23 alert you to take a closer look, correct?

24 A. Correct.

25 MR. EPPICH: Object to the

1 form.

2 QUESTIONS BY MS. SINGER:

3 Q. Okay. And if the prescriber is
4 prescribing at very high doses, again, one
5 factor, depending on their specialty and
6 patients, that might alert a registrant to
7 potential diversion, correct?

8 MR. EPPICH: Object to the
9 form. Foundation. Calls for
10 speculation. Calls for a legal
11 conclusion.

12 THE WITNESS: Correct.

13 QUESTIONS BY MS. SINGER:

14 Q. Okay. And these are the kinds
15 of commonsense red flags that a registrant
16 should know to apply without the DEA telling
17 them to apply them, correct?

18 MR. EPPICH: Object to form.
19 Foundation. Calls for speculation.

20 MR. FINKELSTEIN: Object to the
21 form.

22 THE WITNESS: Can you repeat
23 it, please?

24 QUESTIONS BY MS. SINGER:

25 Q. These are the kinds of

1 commonsense red flags that a registrant
2 should know to apply in looking for diversion
3 without the DEA telling them specifically to
4 look for them, correct?

5 MR. EPPICH: Same objections.

6 THE WITNESS: Yes.

7 (Prevoznik Plaintiff's Exhibit
8 P50 marked for identification.)

9 QUESTIONS BY MS. SINGER:

10 Q. I'm showing you Exhibit 50,
11 Mr. Prevoznik. These are two -- oh, I'm
12 sorry, this is a prescriber in Solon, Ohio.
13 I'm sorry. I'm not -- okay.
14 Dr. Akhtar-Zaidi in Solon, Ohio.

15 And it says here, "Wrote over
16 21,000 opioid prescriptions in 2011 when the
17 average doctor in his specialty wrote 500."

18 Would the DEA consider that to
19 be a red flag of potential diversion?

20 MR. MAHADY: Object to form.

21 Objection. Foundation. Objection to
22 the scope. Outside the Touhy
23 authorization.

24 MR. FINKELSTEIN: Hang on.

25 MR. MAHADY: And also, where is

1 this information from, what is this
2 document? Where was it created? Was
3 it created by the plaintiffs?

4 MS. MAINIGI: It says an expert
5 report of Lacey Keller.

6 MR. FINKELSTEIN: Additionally,
7 information concerning this doctor may
8 be subject to various law enforcement
9 privileges, and it's outside the
10 scope.

11 But I'm going to specifically
12 instruct you not to testify about
13 ongoing investigations.

14 QUESTIONS BY MS. SINGER:

15 Q. So would writing 21,000
16 prescriptions in a year when the average
17 doctor in the same specialty wrote 500 be a
18 red flag of potential diversion to the DEA?

19 MR. EPPICH: Object to form.

20 MR. MAHADY: Objection to form.

21 Objection to scope. Incomplete
22 hypothetical. Foundation.

23 THE WITNESS: Yes.

24 QUESTIONS BY MS. SINGER:

25 Q. Okay. And then turning to the

1 next page of that slide. I'm sorry --

2 A. I don't have it.

3 Q. Okay. Sorry.

4 (Prevoznik Plaintiff's Exhibits
5 P51 and P52 marked for
6 identification.)

7 QUESTIONS BY MS. SINGER:

8 Q. Showing you slide 51,
9 Dr. Adolph Harper in Akron, Ohio.

10 I'm also going to show you the
11 sentencing memo. We'll mark that as
12 Exhibit 52.

13 MR. FINKELSTEIN: So while
14 we're shuffling paper, I can get my
15 concerns and objection on the record.

16 My understanding is that the
17 task force officers have been
18 authorized to give testimony about
19 this doctor and this information. I
20 can tell you this witness has not been
21 prepped to.

22 And so I'm going to instruct
23 you not to answer questions about this
24 specific doctor.

25 And I think you have a witness

1 who will.

2 MS. SINGER: All right. I'm
3 only asking about whether these are
4 red flags generally.

5 MR. FINKELSTEIN: You can
6 answer about general red flags.

7 MS. SINGER: Okay.

8 QUESTIONS BY MS. SINGER:

9 Q. So if you turn on exhibit --
10 which exhibit is this? 53? 52?

11 Okay. The sentencing memo --

12 MR. COOPER: Do you have an
13 extra copy of the sentencing memo?

14 QUESTIONS BY MS. SINGER:

15 Q. Which is PLTF_2804_000013676.
16 It's the government's sentencing memo,
17 memorandum in United States of America versus
18 Adolph Harper.

19 You on the right document?

20 A. Uh-huh, yes.

21 Q. Okay. And if you turn to
22 page 4, in the second paragraph, the first
23 full paragraph of the page, it says, "The
24 atmosphere of Harper's office, like his
25 prescribing practices, was more akin to a

1 street-level drug trafficking operation
2 rather than medical office. Harper's
3 customers waited for hours to see Harper.
4 Many of those customers exhibited behaviors
5 consistent with drug abuse. Witnesses
6 reported seeing customers passed out in the
7 hallway and office while waiting to see
8 Harper, were vomiting or urinating on the
9 floor while waiting in the waiting room.
10 Customers were also combative and aggressive
11 with Harper's staff members if there was any
12 delay in receiving their drugs."

13 Would a registrant observing
14 this medical office have seen a red flag of
15 potential diversion?

16 MR. MAHADY: Objection to form.
17 Objection to foundation. Outside the
18 scope of the Touhy authorization as
19 the government just explained it.

20 Question specifically relates
21 to a doctor whose name was used at
22 least four or five times in forming
23 your question.

24 THE WITNESS: Can you repeat
25 it?

1 QUESTIONS BY MS. SINGER:

2 Q. Yes.

3 Would those signs observed by a
4 registrant about a prescriber's practice have
5 been red flags of potential diversion?

6 MR. MAHADY: Same objections.

7 THE WITNESS: Yes.

8 QUESTIONS BY MS. SINGER:

9 Q. Are these kinds of red flags
10 that we just went through with these two
11 prescribers things that registrants who are
12 observing the practices or seeing this data
13 should have been able to figure out for
14 themselves, should have been able to identify
15 them as red flags?

16 MR. MAHADY: Objection to form.
17 Foundation. Same objection regarding
18 the scope.

19 THE WITNESS: Yes.

20 QUESTIONS BY MS. SINGER:

21 Q. Did a manufacturer who observed
22 a doctor's office that looked like a drug
23 trafficking operation, with patients passed
24 out or vomiting in the office or urinating on
25 themselves, have a duty to do more than just

1 stopping to market to that doctor but also to
2 report that doctor to the DEA?

3 MR. COOPER: Objection. Form.
4 Foundation. Scope.

5 MR. FINKELSTEIN: Objection.
6 Foundation. Incomplete hypothetical.

7 THE WITNESS: Could you repeat
8 it?

9 QUESTIONS BY MS. SINGER:

10 Q. Did a manufacturer who observed
11 that kind of practice that we just described
12 have an obligation to report that doctor to
13 the DEA or other law enforcement or just to
14 stop marketing to that doctor? Would that
15 have been enough?

16 MR. O'CONNOR: Objection.
17 Form. Foundation. Scope.

18 MR. EPPICH: Objection.
19 Incomplete hypothetical.

20 THE WITNESS: So I just want to
21 make sure I'm clear on the question.

22 If the manufacturer had seen
23 this?

24 QUESTIONS BY MS. SINGER:

25 Q. That's correct.

1 A. Right.

2 They should stop shipments?

3 Q. Is it enough to stop marketing
4 to the doctor, or do they also have to report
5 that doctor as part of maintaining effective
6 controls to prevent diversion?

7 MR. O'CONNOR: Same objections.

8 THE WITNESS: I mean, they
9 should be telling us that.

10 QUESTIONS BY MS. SINGER:

11 Q. Now, does the fact that there
12 are bad doctors who are writing illegitimate
13 prescriptions or pharmacies that are
14 dispensing illegally relieve distributors or
15 manufacturers of their duty to review their
16 own information and data for suspicious
17 orders and signs of diversion?

18 MS. MAINIGI: Objection.

19 Vague. Objection. Outside the scope
20 of the Touhy authorization.

21 Objection. Foundation.

22 MR. FINKELSTEIN: I'll object
23 to the form.

24 THE WITNESS: No.

25

1 QUESTIONS BY MS. SINGER:

2 Q. And in fact, in a closed
3 system, the participants in the supply chain,
4 those who are on the inside, have a duty to
5 look out for bad doctors and bad pharmacies,
6 correct?

7 MR. EPPICH: Object to the
8 form. Foundation. Calls for a legal
9 conclusion.

10 THE WITNESS: Yes.

11 (Prevoznik Plaintiff's Exhibit
12 P53 marked for identification.)

13 QUESTIONS BY MS. SINGER:

14 Q. Okay. Let's go to the -- I'm
15 going to show you Exhibit 53. No Bates
16 number, just monkeys.

17 Do you recognize this image of
18 the see no evil, hear no evil, speak no evil,
19 Mr. Prevoznik?

20 A. Yes.

21 MR. MAHADY: Objection. Form.
22 Foundation. Relevance to anything.

23 MS. MAINIGI: It's completely
24 outside the scope of the Touhy
25 authorization. I think it's highly

1 inappropriate to be marking this in a
2 deposition.

3 QUESTIONS BY MS. SINGER:

4 Q. Do registrants who close their
5 eyes, fail to report signs of suspicious
6 order, comply with the Controlled Substances
7 Act?

8 MR. MAHADY: Objection. Form.
9 Foundation. Calls for a legal
10 conclusion.

11 THE WITNESS: No, they don't.

12 QUESTIONS BY MS. SINGER:

13 Q. We can take down the monkeys.
14 They're probably not compliant with the CSA
15 either.

16 MR. EPPICH: Objection.

17 QUESTIONS BY MS. SINGER:

18 Q. You testified before that the
19 DEA doesn't know what range of information
20 registrants have available to them, correct?

21 A. Correct.

22 Q. And they don't have to share
23 with the DEA all the data and information
24 they have on their customers, correct?

25 A. Correct.

1 Q. Now, you talked about the fact
2 that DEA doesn't set a formula or a threshold
3 for industry to apply, correct?

4 A. Correct.

5 Q. And is that -- is the reason
6 for that because the DEA wouldn't necessarily
7 be able to capture what the industry knows
8 about its own customers in setting a
9 threshold?

10 MR. EPPICH: Object to the
11 form. Vague.

12 THE WITNESS: I think it's
13 part -- a part of -- certainly that's
14 part of it, but the other part would
15 also be we don't regulate the practice
16 of medicine, so we're not interfering
17 with what doctors are doing to treat
18 their patients.

19 So in discussions with -- when
20 these thresholds and things -- it also
21 affects the opposite side. So it's
22 not only the diverted side, but it's
23 also legitimate patients who can't get
24 them because of these thresholds that
25 are in place. So it's affecting both

1 sides of the -- it's a delicate
2 balance.

3 QUESTIONS BY MS. SINGER:

4 Q. And so you leave that to a
5 registrant who has all of that information,
6 correct?

7 MR. EPPICH: Objection.
8 Foundation. Form.

9 THE WITNESS: Correct.

10 QUESTIONS BY MS. SINGER:

11 Q. Okay. And the danger is if the
12 DEA were to set the threshold too high, it
13 wouldn't be a real check on identifying
14 suspicious orders, correct?

15 MR. EPPICH: Object to the
16 form. Incomplete hypothetical.

17 MS. MAINIGI: Speculation.

18 THE WITNESS: Yes.

19 QUESTIONS BY MS. SINGER:

20 Q. And if you set it too low, as
21 you said, patients might not be able to get
22 medicine they need, correct?

23 MR. EPPICH: Object to the
24 form. Incomplete hypothetical. Calls
25 for speculation.

1 THE WITNESS: Yes.

2 QUESTIONS BY MS. SINGER:

3 Q. And so it's not that the DEA
4 has some answer on what the threshold should
5 be and isn't telling industry; it's that the
6 DEA is actually saying that industry knows
7 better from its own customers, correct?

8 MR. EPPICH: Object to the
9 form. Calls for speculation.

10 THE WITNESS: They're in a
11 better position than we are.

12 (Prevoznik Plaintiff's Exhibit
13 P54 marked for identification.)

14 QUESTIONS BY MS. SINGER:

15 Q. Okay. So let's go to -- I'm
16 showing you Exhibit 54.

17 So do you recognize
18 MNK-T1_0008504654?

19 A. I recognize the names.

20 Q. Okay. Which names do you
21 recognize?

22 A. Mark Caverly and James
23 Crawford.

24 Q. And who are they?

25 A. Former employees of DEA.

1 Q. Okay. And it says -- if you
2 look down this document, you see
3 Mr. Crawford, I think, three paragraphs from
4 the bottom. Okay. I'm sorry, let's go up
5 from that to the question.

6 "During the distributor
7 breakout session, suspicious order monitoring
8 was certainly a hotbed of discussion. Are
9 there any plans for DEA to publicize
10 information to implement SOM, or suspicious
11 order monitoring, incorporate algorithms
12 where products are more likely to be
13 diverted?"

14 Do you see where I'm reading?

15 A. Yes.

16 Q. Okay. And then can you read
17 Mr. Crawford's response?

18 A. "Whatever we put out will be
19 outdated by the time we put it out. You're
20 looking at a number. Tell me how much --
21 tell me how much that we can't exceed. DEA
22 can't do that. It's part of your due
23 diligence, knowing your customer."

24 Q. And does that reflect what you
25 just testified to in the guidance that DEA

1 gave industry?

2 A. Yes.

3 MR. MAHADY: Objection. Form.

4 THE WITNESS: Yes.

5 QUESTIONS BY MS. SINGER:

6 Q. And then can you read

7 Mr. Caverly's comment at the bottom of the
8 page?

9 A. From the question "What does
10 the DEA expect?"

11 Q. That's right.

12 A. "Previously, DEA sat down with
13 the National Drug Association with an
14 algorithm DEA standpoint - you know your
15 customers better than we do. DEA stepped
16 away from providing guidelines. It's not
17 going to happen."

18 Q. Does that also reflect DEA's
19 view as to why it wouldn't provide a
20 threshold to industry?

21 MR. EPPICH: Object to the
22 form. Foundation. Calls for
23 speculation.

24 THE WITNESS: Yes.

25 (Prevoznik Plaintiff's Exhibit

1 P55 marked for identification.)

2 QUESTIONS BY MS. SINGER:

3 Q. Okay. Showing you Exhibit 55.
4 My goal here is to make your pile go up and
5 mine go down.

6 All right. This is
7 MCKMDL00561303, executive summary regarding
8 the HDMA document.

9 Have you seen this document
10 before, Mr. Prevoznik?

11 A. I'm not sure.

12 Q. Okay. Let me direct you to the
13 last page, Bates number 306. It says in that
14 top bullet to question 10, "This is another
15 area that we have made great strides in over
16 the past few years. Our analytical
17 capabilities provide us with greater insight
18 into our own customer base. We have this
19 data already and frankly are in a position to
20 provide better information to DEA than they
21 could provide to us."

22 Does DEA agree with that
23 statement?

24 MR. EPPICH: Object to the
25 form. Foundation.

1 THE WITNESS: Yes.

2 QUESTIONS BY MS. SINGER:

3 Q. And it says as a sidenote, "DEA
4 does not have dispensing data, nor do they
5 have noncontrol data," correct?

6 A. Correct.

7 Q. Okay. All right. Let's move
8 to -- no, new area.

9 In the first two days of your
10 deposition, you were offered -- you were
11 asked a series of questions about things DEA
12 could have done differently: Did you set up
13 task forces or use ARCOS platforms in a
14 different way.

15 Do you remember that line of
16 questioning?

17 A. Yes.

18 Q. Now, when you came into DEA,
19 what was your first position?

20 A. Diversion investigator in the
21 Philadelphia field office.

22 Q. Okay. So you were out there
23 doing investigations and inspections and
24 building cases, correct?

25 A. Correct.

1 Q. Okay. Based on your experience
2 in all of your years at DEA in management and
3 as a diversion investigator and as the
4 representative of the DEA here today, did DEA
5 make the best judgments it could at the time
6 to use your authority and resources most
7 effectively to prevent diversion?

8 MR. EPPICH: Object to form.
9 Vague.

10 MS. MAINIGI: And objection.
11 Outside the scope of the Touhy
12 authorization.

13 THE WITNESS: Yes, I think we
14 did.

15 QUESTIONS BY MS. SINGER:

16 Q. Had distributors reported
17 suspicious orders to the DEA as the law
18 required would DEA have been able to use its
19 resources more effectively to identify and
20 prevent diversion?

21 MR. EPPICH: Object to the
22 form. Calls for a legal conclusion.
23 Vague.

24 MS. MAINIGI: And outside the
25 scope of the Touhy authorization.

1 MS. DO AMARAL: Incomplete
2 hypothetical.

3 THE WITNESS: I believe so.

4 MR. EPPICH: I second the
5 outside the scope of the Touhy
6 authorization.

7 QUESTIONS BY MS. SINGER:

8 Q. Could you state your answer
9 again?

10 A. I believe so.

11 Q. Okay. And if registrants had
12 reported suspicious orders to the DEA, does
13 the DEA believe that there would have been
14 less diversion, less abuse and less death?

15 MR. EPPICH: Objection. Form.
16 Foundation. Calls for speculation.
17 Incomplete hypothetical. Outside the
18 scope of the Touhy authorization.

19 MR. FINKELSTEIN: Scope. Calls
20 for speculation.

21 THE WITNESS: Yes.

22 QUESTIONS BY MS. SINGER:

23 Q. Would you agree that this line
24 of questions about what the DEA could have
25 done or should have done sounds a lot like

1 blaming the DEA for not catching industry at
2 breaking the law?

3 MR. EPPICH: Object to the
4 form. Foundation. Incomplete
5 hypothetical. Outside the scope of
6 the Touhy authorization.

7 MR. FINKELSTEIN: Scope. Calls
8 for speculation.

9 THE WITNESS: Could you please
10 repeat it?

11 QUESTIONS BY MS. SINGER:

12 Q. Would you agree that this line
13 of questions about what the DEA could have
14 done and should have done sounds a lot like
15 blaming the DEA for not catching the industry
16 in breaking the law?

17 MR. EPPICH: Same objections.

18 MR. FINKELSTEIN: Same
19 objections.

20 THE WITNESS: You're asking me
21 personally?

22 QUESTIONS BY MS. SINGER:

23 Q. Yes.

24 MR. EPPICH: Same objections.

25 THE WITNESS: Me, personally,

1 it certainly would have made a huge
2 difference.

3 QUESTIONS BY MS. SINGER:

4 Q. Does the obligation to maintain
5 effective controls to prevent diversion exist
6 whether or not you are caught?

7 MR. EPPICH: Objection to the
8 form. Incomplete hypothetical. Calls
9 for a legal conclusion. Outside the
10 scope of the Touhy authorization as it
11 may divulge the deliberative process
12 of the DEA.

13 MR. FINKELSTEIN: I appreciate
14 your concern about our deliberative
15 process.

16 You can answer.

17 THE WITNESS: Yes.

18 QUESTIONS BY MS. SINGER:

19 Q. And is it true that the cost of
20 doing a business, of getting a license that
21 allows you to make money by making and
22 selling and distributing narcotics, is that
23 you have to do your best to follow the law
24 and prevent those narcotics from ending up
25 on -- in the street or in the pockets of a

1 12-year-old or anyplace else they shouldn't
2 be?

3 MR. EPPICH: Object to the
4 form. Incomplete hypothetical. Calls
5 for a legal conclusion. Scope.
6 Vague.

7 MR. FINKELSTEIN: I'll object
8 to the form.

9 THE WITNESS: Yes.

10 QUESTIONS BY MS. SINGER:

11 Q. And do you think there's
12 anything about that rule that isn't clear or
13 fair to registrants?

14 MR. EPPICH: Object to the
15 form. Vague. Incomplete
16 hypothetical. Scope. Calls for a
17 legal conclusion.

18 MR. FINKELSTEIN: I'm going to
19 object that that's outside the scope
20 of the Touhy authorization.

21 You can answer in your personal
22 capacity.

23 THE WITNESS: Could you please
24 repeat it?

25

1 QUESTIONS BY MS. SINGER:

2 Q. I have to scroll back through a
3 lot of objections.

4 Is there anything about that
5 rule, to follow the law to prevent diversion,
6 that isn't clear or fair to registrants?

7 MR. EPPICH: Same objections.

8 THE WITNESS: My personal
9 perspective, no, there isn't.

10 (Prevoznik Plaintiff's Exhibit
11 P56 marked for identification.)

12 QUESTIONS BY MS. SINGER:

13 Q. I'm going to show you
14 Exhibit 56.

15 Mr. Prevoznik, this is our
16 effort to put in a timeline the actions DEA
17 took against defendants in this litigation.

18 Does this capture the major
19 enforcement initiatives that DEA took against
20 distributors, manufacturers and distributors,
21 including pharmacies?

22 MR. EPPICH: Object to the
23 form. Objection. Foundation.

24 Objection to inaccuracy of the data
25 that may or may not be in the

1 document.

2 MS. MAINIGI: Outside the scope
3 of the Touhy authorization.

4 MR. FINKELSTEIN: Yeah, I'm
5 going to repeat my concern about the
6 scope. You've been authorized to
7 testify about administrative actions
8 in closed settlements with the
9 defendants.

10 MS. SINGER: That's what's
11 here.

12 MR. FINKELSTEIN: If you're
13 representing that, then subject to
14 that instruction, you can answer.

15 MR. MAHADY: I'm also going to
16 object to the extent that the
17 demonstrative clearly shows things
18 that are not an enforcement action,
19 including references to letters --

20 MS. MAINIGI: Right.

21 MR. MAHADY: -- that are not
22 from the DEA, DOJ and, in fact, come
23 from the defendant.

24 MS. MAINIGI: That is not what
25 it is represented by plaintiffs to be.

1 MR. RUIZ: Also object in it
2 lists the alleged enforcement actions
3 and do not relate to distribution.

4 MR. MAHADY: And enforcement
5 actions by the state courts.

6 MS. SINGER: So these are all
7 facts that have been established or
8 will be established in the course of
9 this litigation.

10 To the extent that defendants
11 have an argument that something here
12 wasn't tied together, that's an
13 argument they can make as to
14 admissibility.

15 MS. MAINIGI: You're asking
16 this corporate representative to
17 somehow bless your document when
18 you've just created it and provided it
19 to him.

20 If you want to go point by
21 point through this document and ask
22 him if he knows about those and
23 whether they're enforcement actions,
24 go ahead.

25 MS. SINGER: So you're welcome

1 to do those questions.

2 QUESTIONS BY MS. SINGER:

3 Q. I'm just asking if this
4 represents the scale and number of
5 enforcement actions that DEA took against the
6 defendants in this litigation.

7 MR. EPPICH: Objection to form
8 and foundation.

9 QUESTIONS BY MS. SINGER:

10 Q. To the extent you know.

11 MR. FINKELSTEIN: And my
12 instruction to you is you're
13 authorized to answer based on
14 administrative actions and/or
15 settlements that the DEA has entered
16 into with any of the defendants, but
17 limit your answer to that.

18 MR. RUIZ: And objection to the
19 extent that this chart has enforcement
20 actions against entities who are not
21 named defendants in this action.

22 MR. FINKELSTEIN: Do you
23 understand my instruction?

24 THE WITNESS: Yeah.

25 It appears to have most of the

1 highlights.

2 QUESTIONS BY MS. SINGER:

3 Q. Okay. And is it fair to say
4 that the DEA has investigated or taken action
5 against virtually every major distributor of
6 opioids over the last 15 years?

7 MR. EPPICH: Object to form and
8 foundation. Calls for speculation.

9 THE WITNESS: Yes.

10 MS. FUMERTON: Also vague.

11 QUESTIONS BY MS. SINGER:

12 Q. And also the major pharmacy
13 chains that distribute opioids?

14 MR. EPPICH: Same objections.

15 THE WITNESS: Yes.

16 QUESTIONS BY MS. SINGER:

17 Q. And also manufacturers like
18 Mallinckrodt and Purdue, correct?

19 MR. EPPICH: Same objections.

20 THE WITNESS: Correct.

21 QUESTIONS BY MS. SINGER:

22 Q. Now, this chart doesn't reflect
23 additional actions that the DEA took against
24 doctors and pharmacists, correct?

25 MR. EPPICH: Objection.

1 Foundation. Calls for speculation.

2 Form.

3 THE WITNESS: Yes.

4 QUESTIONS BY MS. SINGER:

5 Q. Or actions you took against
6 independent pharmacies.

7 And I take it the DEA also took
8 enforcement action against non-chain
9 pharmacies, correct?

10 MR. EPPICH: Objection.

11 Foundation. Calls for speculation.

12 Form.

13 MR. FINKELSTEIN: Scope. I
14 don't want to ask questions.

15 You can answer in your personal
16 capacity.

17 THE WITNESS: Yes. In my
18 personal capacity, yes, we would.

19 QUESTIONS BY MS. SINGER:

20 Q. Okay. So this isn't everything
21 the DEA did in this time period, correct?

22 A. Correct.

23 Q. Okay. All right. Moving on.

24 Now, industry has talked about
25 their inability to get access to ARCOS data

1 on other distributors, correct?

2 Do you remember those
3 questions?

4 A. Yes.

5 Q. Okay. Now, isn't it true that
6 even without information on a competitor's
7 orders, that registrants can identify
8 suspicious orders and potential diversion?

9 MR. EPPICH: Objection to form.
10 Foundation. Calls for speculation.

11 THE WITNESS: So essentially
12 their own data.

13 QUESTIONS BY MS. SINGER:

14 Q. Yes.

15 A. Yes.

16 Q. Okay. And when you've taken --
17 when you, the DEA, has taken enforcement
18 actions or entered into settlement agreements
19 with registrants, you've looked at their own
20 data, correct?

21 A. Yes.

22 Q. And what those registrants
23 should have known or did know about their own
24 customers, correct?

25 A. Correct.

1 MR. EPPICH: Object to the
2 form.

3 QUESTIONS BY MS. SINGER:

4 Q. And you haven't taken those
5 actions based on data from other registrants,
6 correct?

7 MR. EPPICH: Object to the
8 form. Vague.

9 THE WITNESS: Correct.

10 QUESTIONS BY MS. SINGER:

11 Q. Right.

12 So just to be perfectly clear,
13 you didn't expect Cardinal to know what
14 McKesson or AmerisourceBergen was supplying
15 to a customer, correct?

16 A. Correct.

17 MS. MAINIGI: Objection. Form.

18 QUESTIONS BY MS. SINGER:

19 Q. Is it the DEA's experience that
20 suspicious orders filled by manufacturers,
21 distributors and pharmacies were suspicious
22 in their own right without anybody else's
23 data?

24 MR. EPPICH: Object to the
25 form. Calls for a legal conclusion.

1 Vague.

2 MR. RUIZ: Foundation.

3 THE WITNESS: Yes.

4 QUESTIONS BY MS. SINGER:

5 Q. And when distributors take on
6 or registrants take on a new customer, DEA
7 recommends that they ask whether that
8 customer uses other distributors, correct?

9 MR. EPPICH: Object to the
10 form. Foundation.

11 THE WITNESS: Yes.

12 QUESTIONS BY MS. SINGER:

13 Q. And with dispensing data -- I'm
14 sorry.

15 And they also -- the DEA also
16 recommends that a registrant obtain -- or a
17 distributor -- let me try that again.

18 DEA also recommends that a
19 distributor obtain dispensing data from a
20 pharmacy before they take them on as a
21 customer, correct?

22 MR. EPPICH: Object to form.
23 Foundation. Vague as to time.

24 THE WITNESS: Yes, if they can
25 get it.

1 QUESTIONS BY MS. SINGER:

2 Q. Okay. And with dispensing
3 data, it would be obvious to a distributor if
4 the pharmacy received controlled substances
5 from more than one distributor, correct?

6 MR. EPPICH: Object to form.
7 Foundation. Calls for speculation.

8 MS. MAINIGI: Outside the scope
9 of the Touhy authorization.

10 MR. FINKELSTEIN: Join in the
11 scope objection.

12 THE WITNESS: Could you run
13 that by me again?

14 QUESTIONS BY MS. SINGER:

15 Q. Yeah, let me try to be clearer
16 in my question.

17 If you get the dispensing
18 data -- if a distributor gets the dispensing
19 data from a customer and it gets more
20 controlled substances than that distributor
21 supplies, then the distributor knows that
22 it's getting controlled substances from other
23 distributors, correct?

24 MR. EPPICH: Object to form.
25 Foundation. Calls for speculation.

1 Outside the scope.

2 THE WITNESS: It could be from
3 another distributor, or it could be
4 from another pharmacy selling stuff to
5 them. So it's not necessarily another
6 distributor. It could be another
7 registrant that's selling them.

8 QUESTIONS BY MS. SINGER:

9 Q. Okay. But it's another
10 supplier other than -- or distributor,
11 correct?

12 A. Yes.

13 MR. EPPICH: Same objections.

14 QUESTIONS BY MS. SINGER:

15 Q. Now, if a pharmacy won't
16 provide dispensing information to a
17 distributor, would that be a red flag that
18 the distributor needs to look more closely at
19 that customer?

20 MR. EPPICH: Object to the
21 form. Vague as to time.

22 MS. MAINIGI: Scope. Outside
23 the scope of the Touhy authorization.

24 MR. FINKELSTEIN: Incomplete
25 hypothetical.

1 MR. EPPICH: Objection. Calls
2 for speculation.

3 THE WITNESS: Yes, they should
4 be.

5 QUESTIONS BY MS. SINGER:

6 Q. They should?

7 A. They should.

8 Q. A distributor should ask?

9 A. Should ask for it.

10 MR. EPPICH: Same objections.

11 QUESTIONS BY MS. SINGER:

12 Q. And if a pharmacy directed a
13 distributor that it should not -- or could
14 not go into its store and talk with its
15 personnel or get a feel for that store,
16 should that be another red flag to that
17 distributor?

18 MR. EPPICH: Same objections.

19 MR. FINKELSTEIN: Incomplete
20 hypothetical.

21 THE WITNESS: Yes.

22 QUESTIONS BY MS. SINGER:

23 Q. Okay. And that's true whether
24 it's a chain pharmacy or an independent
25 pharmacy, correct?

1 MR. EPPICH: Same objections.

2 THE WITNESS: Correct.

3 QUESTIONS BY MS. SINGER:

4 Q. Now, distributors have
5 information on both controlled and
6 noncontrolled substances that are ordered by
7 a customer, correct?

8 MR. EPPICH: Objection.

9 Foundation. Form and vague.

10 THE WITNESS: Yes.

11 QUESTIONS BY MS. SINGER:

12 Q. And that lets them see where a
13 customer's order of controlled substances is
14 disproportionate to its other orders,
15 correct?

16 MR. EPPICH: Objection. Form.

17 Foundation. Calls for speculation.

18 Vague.

19 THE WITNESS: Yes.

20 QUESTIONS BY MS. SINGER:

21 Q. And so if a customer is
22 ordering a lot of opioids and very little
23 antibiotics or diabetes medicine, that would
24 be one potential red flag of diversion,
25 correct?

1 MR. EPPICH: Objection. Form.
2 Foundation. Calls for a legal
3 conclusion.

4 THE WITNESS: Yes, it could
5 potentially be a red flag.

6 QUESTIONS BY MS. SINGER:

7 Q. A red flag?

8 A. Yes.

9 Q. Okay. And it's also true that
10 pharmacies that order a certain mix of drugs
11 that are abused together, that that can be
12 another red flag of potential diversion,
13 correct?

14 MR. EPPICH: Objection. Form.
15 Foundation. Calls for a legal
16 conclusion.

17 THE WITNESS: Yes.

18 QUESTIONS BY MS. SINGER:

19 Q. Now, distributors have that
20 data on other noncontrolled substance orders,
21 correct?

22 MR. EPPICH: Objection. Form.
23 Foundation. Calls for speculation.

24 MR. FINKELSTEIN: Scope. Calls
25 for speculation.

1 THE WITNESS: Yes.

2 QUESTIONS BY MS. SINGER:

3 Q. But DEA doesn't get reporting
4 from distributors on noncontrolled substances
5 ordered by customers, correct?

6 A. No, we do not.

7 We do have some distributors
8 that have told us -- like now everybody is
9 looking at gabapentin, so the distributors
10 have said, "We are going to take a harder
11 look at that, that one."

12 Q. Okay. But in general, and
13 certainly over the time period we've been
14 talking about from 1996 until now, you --

15 A. There's been -- I mean, there's
16 been other substances that they've said --
17 you know, I remember ketamine. That was one
18 they said, oh, it was not a noncontrol and we
19 made it controlled.

20 So there's been other drugs
21 that they have stepped up and said, you know,
22 "We need to keep an eye on these. We're
23 going to -- can we put them in the controlled
24 substance cage because we are seeing that?"
25 So we have had those dialogs with them as

1 well.

2 Q. Okay. But you don't routinely
3 get antibiotics or other non-diverted or
4 abused drugs, correct?

5 MR. EPPICH: Objection. Asked
6 and answered. Form.

7 THE WITNESS: Correct.

8 QUESTIONS BY MS. SINGER:

9 Q. And DEA doesn't have
10 prescribing information in ARCOS, correct?

11 MR. EPPICH: Objection. Form.
12 Vague.

13 THE WITNESS: Correct.

14 QUESTIONS BY MS. SINGER:

15 Q. But that information is
16 certainly useful in detecting suspicious
17 orders or potential diversion, correct?

18 MR. EPPICH: Objection. Calls
19 for a legal conclusion. Form.

20 THE WITNESS: Correct.

21 QUESTIONS BY MS. SINGER:

22 Q. Is DEA aware that registrants
23 have information -- have access to
24 information on cash payments that are
25 received by pharmacies?

1 MR. EPPICH: Objection. Form.

2 Calls for speculation.

3 MR. FINKELSTEIN: Scope. Calls

4 for speculation.

5 THE WITNESS: I believe we do.

6 I believe they do.

7 QUESTIONS BY MS. SINGER:

8 Q. They do?

9 A. Yeah.

10 Q. And does DEA have that
11 information?

12 MR. EPPICH: Objection.

13 THE WITNESS: If we subpoena
14 it.

15 QUESTIONS BY MS. SINGER:

16 Q. Okay. But not in the regular
17 course --

18 A. No.

19 Q. -- of identifying potential
20 diversion?

21 A. Right.

22 Q. Now, does ARCOS data tell you
23 whether a customer is near a hospital or a
24 cancer center or a hospice treatment
25 facility?

1 A. No, it's just transactional
2 data.

3 Q. Okay. But distributors and
4 manufacturers would learn that information in
5 their due diligence on customers, correct?

6 MR. EPPICH: Objection. Form.
7 Foundation. Calls for speculation.

8 THE WITNESS: Yes.

9 QUESTIONS BY MS. SINGER:

10 Q. Okay. And when you get, for
11 instance, a -- when you, DEA, gets, for
12 instance, a big stack of ingredient limit
13 reports, you can't tell from that whether
14 orders of large numbers are by facilities
15 that are near hospitals or oncology centers
16 or anything like that, correct?

17 MR. EPPICH: Object to the
18 form.

19 THE WITNESS: I'm sorry, could
20 you repeat it?

21 QUESTIONS BY MS. SINGER:

22 Q. So when you get, you know, a
23 big stack of excess order reports or
24 ingredient limit reports, you can't tell if a
25 large order is from a customer that's near an

1 oncology center or a hospital, for instance,
2 correct?

3 MR. EPPICH: Object to the
4 form.

5 THE WITNESS: Correct. From
6 the reports, you cannot.

7 QUESTIONS BY MS. SINGER:

8 Q. Does the DEA get chargeback
9 data?

10 A. No.

11 (Prevoznik Plaintiff's Exhibit
12 P57 marked for identification.)

13 QUESTIONS BY MS. SINGER:

14 Q. All right. Let's go to the
15 letter. Exhibit 57.

16 This is a letter from the
17 DEA -- I'm sorry, from the Department of
18 Justice to the Honorable Dan A. Polster dated
19 January 30, 2018.

20 Have you seen this letter?

21 A. Yes.

22 Q. Okay. And it's signed by
23 Demetra Ashley --

24 A. Yes.

25 Q. -- is that correct?

1 Okay. And this represents the
2 official position of the Department of
3 Justice and DEA, correct?

4 MR. EPPICH: Objection. Form.
5 Foundation.

6 THE WITNESS: Yes.

7 QUESTIONS BY MS. SINGER:

8 Q. Okay. Turning to page 4,
9 please. The middle paragraph, second
10 sentence says, "Release of the personally
11 identifiable information of individual
12 registrants without their consent would
13 violate the Privacy Act."

14 Do you see where I'm reading?

15 A. Yes.

16 Q. "Therefore, DOJ objects to the
17 production thereof under its Touhy
18 regulations. Disclosure would improperly
19 reveal trade secrets without the owners'
20 consent, and, therefore, the DOJ objects to
21 the production thereof under its Touhy
22 regulations," citing them. "Production of
23 this data would reveal specific details
24 regarding the scope and breadth of their
25 market share, which is likely to cause

1 manufacturers and distributors substantial
2 competitive harm."

3 Have I read that correctly?

4 A. Yes.

5 Q. Okay. And it goes on to say,
6 "In Freedom of Information Act litigation,
7 registrants have articulated the competitive
8 harm that would result from the release of
9 this information in several ways. For
10 example, registrants have expressed concern
11 that ARCOS information, if made publicly
12 available, could be used by competitors to
13 determine market share and sales trends in
14 specific areas and would enable competitors
15 to target existing customers and attempt to
16 take away business. For" --

17 So have I read all of that
18 correctly?

19 A. Yes.

20 Q. "For this reason, registrants
21 have repeatedly asserted that they rely on
22 DEA to protect the confidential business
23 information that they report to DEA through
24 ARCOS."

25 Have I read that correctly?

1 A. Yes.

2 Q. And is it the DEA's experience
3 that registrants have objected to sharing
4 ARCOS data with their competitors?

5 A. Yes.

6 MR. EPPICH: Object to form and
7 foundation.

8 QUESTIONS BY MS. SINGER:

9 Q. All right. You can put that
10 aside.

11 So all registrants have the
12 same duty to maintain effective controls to
13 protect diversion and to detect, report and
14 stop shipment of suspicious orders; is that
15 correct?

16 MR. EPPICH: Objection. Calls
17 for a legal conclusion.

18 MS. FUMERTON: Objection.
19 Form.

20 THE WITNESS: Yes.

21 QUESTIONS BY MS. SINGER:

22 Q. And I think you testified
23 before that the obligation depends on where
24 you sit in the supply chain.

25 Do you remember that?

1 MR. EPPICH: Objection.

2 THE WITNESS: You mean in terms

3 of --

4 QUESTIONS BY MS. SINGER:

5 Q. Let me put it a different way
6 rather than focusing on what you testified
7 to.

8 Is it true that your
9 obligations are the same, but what you may
10 observe and have data on depends on where you
11 are in the supply chain, correct?

12 MR. EPPICH: Object to the
13 form. Vague.

14 THE WITNESS: Yes.

15 QUESTIONS BY MS. SINGER:

16 Q. So you have the same
17 obligation -- or a registrant has the same
18 obligation to report and prevent diversion,
19 regardless of where they are in the supply
20 chain, correct?

21 MR. EPPICH: Object to the
22 form. Calls for a legal conclusion.

23 THE WITNESS: Correct.

24 QUESTIONS BY MS. SINGER:

25 Q. And the difference is what

1 diversion you can see from where you sit,
2 correct?

3 MR. EPPICH: Objection to form.

4 Calls for a legal conclusion. Vague.

5 THE WITNESS: Yes.

6 QUESTIONS BY MS. SINGER:

7 Q. And if a registrant has
8 information that would alert it to diversion,
9 it has an obligation under the Controlled
10 Substances Act to use that information to
11 prevent diversion, correct?

12 MR. EPPICH: Object to form.

13 Calls for a legal conclusion. Vague.

14 THE WITNESS: Correct.

15 QUESTIONS BY MS. SINGER:

16 Q. And you can't be like that
17 monkey, hiding your eyes --

18 MR. EPPICH: Objection.

19 QUESTIONS BY MS. SINGER:

20 Q. -- and say, "We only use that
21 data for marketing" --

22 MR. EPPICH: Objection.

23 QUESTIONS BY MS. SINGER:

24 Q. -- "or accounting."

25 You have to use that data for

1 compliance, too, correct?

2 MR. EPPICH: Objection.

3 THE WITNESS: Yes.

4 QUESTIONS BY MS. SINGER:

5 Q. Before manufacturers sell
6 opioids to a distributor, that manufacturer
7 must make sure that the distributor has an
8 adequate and effective suspicious order
9 monitoring program, correct?

10 MR. O'CONNOR: Objection.

11 Form. Foundation.

12 THE WITNESS: Yes.

13 QUESTIONS BY MS. SINGER:

14 Q. And that would include doing a
15 site visit of the distributor, correct?

16 MR. O'CONNOR: Objection.

17 Form.

18 THE WITNESS: Yes.

19 QUESTIONS BY MS. SINGER:

20 Q. And examining its suspicious
21 order monitoring program, correct?

22 A. Yes.

23 Q. And if a manufacturer sees
24 evidence that a distributor is shipping and
25 failing to report suspicious orders, that

1 should suggest to the manufacturer that the
2 distributor does not have effective controls,
3 correct?

4 MR. O'CONNOR: Objection.
5 Form.

6 MS. MACKAY: Incomplete
7 hypothetical.

8 THE WITNESS: Correct.

9 QUESTIONS BY MS. SINGER:

10 Q. And if the information a
11 manufacturer has available to them points to
12 diversion by prescribers, by pharmacies, a
13 manufacturer has an obligation to notify DEA
14 of those prescribers and pharmacies, correct?

15 MR. O'CONNOR: Objection.
16 Form. Incomplete hypothetical.

17 THE WITNESS: Yes.

18 QUESTIONS BY MS. SINGER:

19 Q. And does a manufacturer comply
20 with its obligations to report suspicious --
21 I'm sorry.

22 Does a manufacturer comply with
23 the Controlled Substances Act when it reports
24 that potential diversion to its distributor
25 but not the DEA?

1 MR. O'CONNOR: Objection.

2 Form.

3 THE WITNESS: I'm sorry, can

4 you run --

5 QUESTIONS BY MS. SINGER:

6 Q. So if the manufacturer only
7 tells its distributor and not the DEA, have
8 they satisfied their obligation under the
9 Controlled Substances Act?

10 MR. O'CONNOR: Objection.

11 Form.

12 MR. FINKELSTEIN: Incomplete
13 hypothetical.

14 THE WITNESS: No.

15 QUESTIONS BY MS. SINGER:

16 Q. Are distributors -- and I'm
17 sorry. Mr. Farrell asked you these questions
18 about chain pharmacies and whether there are
19 different compliance obligations for chain
20 pharmacies.

21 Do you remember that?

22 A. Yes.

23 Q. And I just want to show you one
24 document.

25 (Prevoznik Plaintiff's Exhibit

1 P58 marked for identification.)

2 QUESTIONS BY MS. SINGER:

3 Q. Exhibit 58. It is
4 DEA_Rannazzisi, a lot of zeros, 6060. It's
5 titled "Declaration of Michael Arpaio."

6 Do you recognize this document?

7 A. No.

8 Q. Okay. Do you know who Michael
9 Arpaio is?

10 A. Yes.

11 Q. And who is that?

12 A. He is a former DEA diversion
13 investigator.

14 Q. Okay. And if you turn to
15 page 2, backside. Now -- I'm sorry, go back
16 to the first page, the caption.

17 Can you read the caption for
18 this, in the matter of Cardinal Health?

19 A. Cardinal Health.

20 Q. Okay. I'm sorry, now read
21 paragraph 5, if you would, please.

22 A. "I told Mr." --

23 Is it Moné?

24 Q. Yes.

25 A. "I told Mr. Moné that due

1 diligence investigations must be performed on
2 all customers."

3 Q. And if you go back for one
4 second, if you read the top line of
5 paragraph 4, it may explain who Mr. Moné is.

6 A. "Consequently, on July 29,
7 2009, I spoke via teleconference to Mike
8 Moné, quality and regulatory affairs vice
9 president, anti-diversion and supply chain
10 services, who is headquartered in Cardinal
11 Health's Dublin, Ohio, facility but at the
12 time was in Washington, DC."

13 Q. Okay. You can stop there.

14 And I'm sorry, if you can pick
15 up where you were in paragraph 5.

16 A. Just start --

17 Q. Just start from the beginning
18 on paragraph 5.

19 A. "I told Mr. Moné that due
20 diligence investigations must be performed on
21 all customers, chain pharmacies included,
22 when it appears that suspicious high volume
23 orders of controlled substances are
24 requested, and questionnaires should be sent
25 to those -- to these chains.

1 "Mr. Moné, in turn, stated that
2 QRA is unable to look at chain pharmacy
3 systems in order to identify problem areas
4 when there is not an order of interest or
5 their threshold is not exceeded. I repeated
6 the chain store due diligence reviews must
7 not be treated any differently than
8 independent retail pharmacy customers."

9 Q. In that last sentence that
10 "chain store due diligence reviews must not
11 be treated any differently than independent
12 retail pharmacy customers," does that
13 represent the view of the DEA?

14 A. Yes.

15 MS. MAINIGI: Objection. Form.
16 QUESTIONS BY MS. SINGER:

17 Q. And that is the guidance that
18 DEA gave to registrants, correct?

19 MS. MAINIGI: Objection to
20 form. Objection. Outside the scope
21 of the Touhy authorization.
22 Objection.

23 MR. EPPICH: Objection to the
24 prior question.

25 MS. MAINIGI: Objection to the

1 prior question and there also to this
2 current question.

3 QUESTIONS BY MS. SINGER:

4 Q. Go ahead.

5 That's the guidance that DEA
6 gave to registrants?

7 A. Correct.

8 Q. All right. Should distributors
9 be looking at all of the volume of opioids
10 they supply into a geographic area in
11 determining whether orders may be suspicious?

12 MR. EPPICH: Object to the
13 form. Foundation. Vague. Calls for
14 a legal conclusion.

15 THE WITNESS: It would
16 definitely help.

17 QUESTIONS BY MS. SINGER:

18 Q. Okay. Meaning if they're
19 supplying in ways that are very
20 disproportionate to the population, that
21 should be a sign that they're not supplying
22 to a legitimate market, correct?

23 MR. EPPICH: Objection to the
24 form. Calls for a legal conclusion.

25 THE WITNESS: Correct.

1 QUESTIONS BY MS. SINGER:

2 Q. And distributors may not know
3 all of the pills that are going into an area,
4 but they certainly know what pills they're
5 sending, correct?

6 MR. EPPICH: Objection to the
7 form. Calls for a legal conclusion.

8 MS. MAINIGI: No foundation.
9 Outside the scope of the Touhy
10 authorization.

11 THE WITNESS: Correct.

12 QUESTIONS BY MS. SINGER:

13 Q. Are orders that are below a
14 threshold set by a distributor sometimes
15 suspicious, too?

16 MR. EPPICH: Objection. Calls
17 for a legal conclusion. Form. Vague.

18 THE WITNESS: Yes, they can be.

19 QUESTIONS BY MS. SINGER:

20 Q. And should registrants be
21 reporting orders that are within threshold
22 but are still suspicious for other reasons?

23 MR. EPPICH: Objection to form.
24 Calls for a legal conclusion. Scope.

25 THE WITNESS: Yes.

1 QUESTIONS BY MS. SINGER:

2 Q. If an order exceeds a threshold
3 set by a registrant, is it no longer
4 suspicious if the registrant cuts the order
5 to threshold and ships it anyway?

6 MR. EPPICH: Objection. Form.
7 Incomplete hypothetical. Calls for a
8 legal conclusion. Vague.

9 MS. MAINIGI: Outside the scope
10 of the Touhy authorization.

11 MR. FINKELSTEIN: Incomplete
12 hypothetical.

13 THE WITNESS: Could you repeat
14 it?

15 QUESTIONS BY MS. SINGER:

16 Q. Yes. Let me do it as an
17 example.

18 If the threshold says that an
19 order of 10,000 dosage units exceeds
20 threshold and a customer orders 50,000 dosage
21 units, can the distributor just cut the order
22 to 10,000 units and ship it without
23 investigating whether it's suspicious or not?

24 MR. EPPICH: Objection. Form.
25 Incomplete hypothetical. Calls for a

1 legal conclusion and vague.

2 THE WITNESS: Well, in your
3 hypothetical it sounded like it was
4 already triggered as a suspicious
5 order, so immediately upon discovery
6 they were supposed to tell us anyway
7 that this happened.

8 QUESTIONS BY MS. SINGER:

9 Q. And shipping less of it doesn't
10 make it not suspicious anymore. If it's a
11 suspicious order, it's a suspicious order,
12 correct?

13 MR. EPPICH: Objection to form.
14 Calls for a legal conclusion.

15 THE WITNESS: Right. So they
16 can either not ship it or they can
17 investigate to determine -- to
18 alleviate the suspicions that they
19 have.

20 QUESTIONS BY MS. SINGER:

21 Q. Okay. Let's go to...
22 (Prevoznik Plaintiff's Exhibit
23 P59 marked for identification.)

24 QUESTIONS BY MS. SINGER:

25 Q. Okay. This is exhibit -- can

1 you see the number, Mr. Prevoznik? I forgot
2 to check it.

3 A. 59.

4 Q. Okay. And do you recognize
5 this as the testimony of Demetra Ashley from
6 the Office of Diversion Control at DEA?

7 A. Yes.

8 Q. I believe it was an exhibit in
9 the first two days of your deposition.

10 A. Yes.

11 Q. All right. And it's dated
12 December 12, 2017, correct?

13 A. Correct.

14 Q. Okay. So I believe that
15 Cardinal's counsel read you some of this, and
16 I just want to complete the record on it.

17 So, first, if you could turn to
18 page 7.

19 Under the title "Ensuring
20 Patient Access and Effective Drug Enforcement
21 Act," first sentence, "The United States is
22 currently facing an opioid epidemic."

23 Is that the view of the DEA?

24 A. Yes.

25 MR. EPPICH: Objection to form.

1 QUESTIONS BY MS. SINGER:

2 Q. And turning the page, I believe
3 you were asked to read the last sentence of
4 the middle paragraph, "The DEA needs every
5 tool."

6 Can you just read the first
7 part of that paragraph, too, so we have a
8 complete record and not just an
9 out-of-context sentence?

10 MR. EPPICH: Object to that
11 commentary.

12 THE WITNESS: "The DEA needs
13 every tool it can to combat the opioid
14 crisis. DEA supports changing the
15 Ensuring Patient Access and Effective
16 Drug Enforcement Act to allow DEA to
17 more effectively stop bad actors from
18 engaging in opioid diversion. We are
19 dealing with very dangerous drugs that
20 can result in addiction and even
21 death."

22 QUESTIONS BY MS. SINGER:

23 Q. Okay. I think that completes
24 the record. You read the last sentence
25 previously.

1 All right. Let's now go to
2 the...

3 MR. FINKELSTEIN: I'm going to
4 ask for our lunch break in a minute.

5 MS. SINGER: Okay. I'm just
6 about done.

7 (Prevoznik Plaintiff's Exhibit
8 P60 marked for identification.)

9 QUESTIONS BY MS. SINGER:

10 Q. Okay. Exhibit 60.

11 And this is
12 DEA_Rannazzisi_00003482. And that title page
13 is "Prescription Opioids to Heroin: A
14 Natural Progression, June 14, 2014, Joseph
15 Rannazzisi."

16 Do you recognize this document?

17 A. Yes.

18 Q. And what do you recognize it
19 as?

20 A. Mr. Rannazzisi's presentation.

21 Q. Okay. And that was an official
22 DEA presentation, correct?

23 A. Correct.

24 Q. Okay. And there aren't slide
25 numbers.

1 Do we have that tabbed?

2 If you could go to the second
3 tab, please, which is titled "Migration of
4 Pain Clinics."

5 Are you at that page with a
6 map?

7 A. Yes.

8 Q. Okay. Can you explain what
9 this map represents in terms of DEA's
10 enforcement?

11 MR. O'CONNOR: Objection.
12 Foundation.

13 MS. MAINIGI: Outside the scope
14 of the Touhy authorization.

15 MR. FINKELSTEIN: You can
16 answer this question, but this will be
17 the last question before our lunch
18 break.

19 THE WITNESS: Okay.

20 What this means is after we
21 took the enforcement actions we did in
22 Florida, this was what the pain -- the
23 bad pain clinics did, the rogue pain
24 clinics did, was they went -- moved --
25 as you can see the directions they

1 moved into. They moved into states
2 that had weak laws governing pain
3 clinics. So this was the movement of
4 the rogue pain clinics from Florida
5 out.

6 QUESTIONS BY MS. SINGER:

7 Q. Okay. And this reflects DEA's
8 experience that when you take enforcement
9 action someplace, the diversion can move into
10 other areas, correct?

11 A. Correct.

12 MS. MAINIGI: Objection.
13 Outside the scope. Vague.

14 VIDEOGRAPHER: Okay. We're
15 going off the record. The time is
16 12:46.

17 (Off the record at 12:46 p.m.)

18 VIDEOGRAPHER: We're going back
19 on the record. Beginning of Media
20 File 5. The time is 1:37.

21 EXAMINATION

22 QUESTIONS BY MR. MAHADY:

23 Q. Mr. Prevoznik, good afternoon.
24 My name is Joe Mahady. I, along with my
25 colleague, Robert Nicholas, are counsel for

1 AmerisourceBergen in this litigation.

2 Before we begin, I do want to
3 sincerely thank you for your patience over
4 last two and a half days. I know it's been a
5 lot, and it is appreciated.

6 I want to start my questioning
7 with the testimony you provided relating to
8 after-the-fact reporting of suspicious
9 orders.

10 Okay?

11 A. Uh-huh.

12 Q. All right. And when we're
13 talking about after-the-fact reporting of
14 suspicious orders, what we are talking about
15 is registrants who report suspicious -- who
16 ship suspicious orders after they've been
17 reported to DEA, correct?

18 A. After they reported it?

19 Q. Yes.

20 After-the-fact reporting is
21 when the suspicious order has been shipped
22 and then reported to DEA; is that correct?

23 A. Those were excessive purchases.

24 Q. Okay.

25 A. So it was after-the-fact sales.

1 Q. Okay. And my understanding of
2 your testimony is that the DEA has always
3 interpreted orders to mean prior to shipment;
4 is that correct?

5 A. Correct.

6 Q. All right. And that the DEA
7 has consistently provided the guidance --
8 that guidance to registrants, correct?

9 A. Correct.

10 Q. All right. And that the DEA
11 has never told registrants that
12 after-the-fact reporting is compliant with
13 federal law; is that correct?

14 A. Well, the use of the term -- of
15 the absolute "never," there might be an
16 employee that did, but DEA policy has always
17 been --

18 Q. Okay. So nobody from DEA
19 headquarters has ever told a registrant, to
20 your knowledge, that after-the-fact reporting
21 is compliant with federal law, correct?

22 A. Well, again, you started it
23 with the "never" -- did somebody at DEA
24 headquarters ever do it. So I'm -- I can't
25 say that somebody didn't say something, but I

1 can say DEA policy is that they should not.

2 Q. Okay. I appreciate that.

3 And I believe you testified
4 that the DEA has consistently advised
5 registrants that they should not ship an
6 order that they report as suspicious; is that
7 correct?

8 A. Correct.

9 Q. And when you say
10 "consistently," you were referring to the
11 time period from 1971 when the Controlled
12 Substances Act was passed until present day;
13 is that right?

14 A. Yes.

15 Q. So approximately a 50-year
16 period. Your testimony is that the DEA
17 guidance on that point has been consistent,
18 correct?

19 A. Correct.

20 Q. All right. You joined the DEA
21 in 1991, correct?

22 A. Yes.

23 Q. In my home city of
24 Philadelphia?

25 A. Yes.

1 Q. Okay.

2 A. Where you from?

3 Q. Philadelphia.

4 Where?

5 A. Yeah.

6 Q. Well, now I'm in the 'burbs.

7 We had to move. But I was in city.

8 So -- and you joined

9 headquarters in 2012, correct?

10 A. Yes.

11 Q. Okay. So I want to understand
12 a little bit better how you can testify that
13 the guidance was consistent for that entire
14 50-year period.

15 Okay?

16 A. Sure.

17 Q. Okay. So in preparing for your
18 deposition as the representative from the
19 DEA, who did you speak with that -- well, let
20 me back up.

21 You don't have any firsthand
22 knowledge of the guidance that the DEA
23 offered from 1971 until you joined the DEA in
24 1991, correct?

25 A. I have the statute and the

1 regulations that haven't changed since then.

2 Q. Okay.

3 A. So that's what I relied on.

4 Q. So you relied -- for the period
5 from 1971 to 1991, you relied entirely on the
6 statute and the regulation, correct?

7 MR. FINKELSTEIN: Objection.

8 Argumentative. Mischaracterizes prior
9 testimony.

10 THE WITNESS: No, because we
11 went through some of the letters that
12 I had seen in the 1980s in which those
13 topics were discussed in there.

14 But I also know that Burles
15 Vulcom {phonetic}, there was a press
16 release that they had to pay a heavy
17 fine back in the 19 -- mid-1980s
18 because they weren't reporting
19 suspicious orders.

20 So I was reviewing documents
21 that would show what was DEA's
22 position and what did we say. So I
23 was looking at correspondence, any
24 correspondence, I could find in the
25 1980s, 1990s, anything that showed

1 that consistent -- what did we say,
2 what was our policy.

3 QUESTIONS BY MR. MAHADY:

4 Q. Okay. And what did we say
5 regarding the guidance relating to reporting
6 a suspicious order and then shipping it.
7 That's what we're talking about specifically,
8 right?

9 A. Right.

10 Q. Okay. Did you speak with
11 anyone at the -- in preparation for your
12 30(b)(6), did you speak with anyone at the
13 DEA who was knowledgeable about the guidance
14 offered by the DEA on that issue from 1971 to
15 1980?

16 MR. FINKELSTEIN: I'm going to
17 object and note for the record that
18 the witness had a prep sheet which was
19 to stay with his prep materials that
20 has not been provided to him today.

21 MR. MAHADY: Okay. And that
22 was a prep sheet that the Department
23 of Justice brought with them last
24 time, so it's not a document that we
25 were to bring. So --

1 MR. FINKELSTEIN: No, it was a
2 document that was marked as an
3 exhibit, provided to everyone and kept
4 with the witness himself, kept with
5 the court reporter, so he could rely
6 on them.

7 MR. MAHADY: Okay.

8 MR. FINKELSTEIN: This
9 specifically listed his prep.

10 MR. MAHADY: Okay. That's
11 fine.

12 MR. FINKELSTEIN: And so now
13 he's going on memory, where we
14 specifically prepared an exhibit for
15 you.

16 MR. MAHADY: I appreciate that.

17 MS. MAINIGI: We'll try to find
18 it. I think the exhibits went with
19 the prior court reporter, so I think
20 that's what happened.

21 MR. MAHADY: Okay.

22 QUESTIONS BY MR. MAHADY:

23 Q. In preparation for your
24 30(b)(6), you did not speak with Michael
25 Mapes, correct?

1 A. No.

2 Q. And you did not speak with Kyle
3 Wright, correct?

4 A. No.

5 Q. There was a reference to a Tom
6 Gitchel earlier today; is that right?

7 A. Tom Gitchel, yes.

8 Q. And who is Tom Gitchel?

9 A. Tom Gitchel was a senior
10 manager within the diversion program at DEA.

11 Q. Okay. And did you speak with
12 Tom Gitchel in preparation for providing
13 testimony on behalf of the DEA?

14 A. No.

15 Q. Okay. How about Patricia Good?
16 Did you speak with Patricia Good?

17 A. No.

18 Q. How many field offices does the
19 DEA have?

20 A. Currently we have 23.

21 Q. Okay. And do you know how many
22 field offices the DEA had in the 1990s?

23 MR. FINKELSTEIN: Objection.

24 Scope.

25 THE WITNESS: I believe it was

1 18 and went to 20.

2 QUESTIONS BY MR. MAHADY:

3 Q. Okay. And in preparing for
4 your deposition as a 30(b)(6) on behalf of
5 the DEA, how many representatives from field
6 offices did you speak with?

7 A. Probably about 10 to 12.

8 Q. Okay.

9 A. Sort of off the top of my head.

10 Q. And how many of those
11 individuals worked at field offices in the
12 1990s?

13 A. Worked in the field offices?

14 Q. Correct.

15 A. Eight to ten of them.

16 Q. Okay. Mr. Prevoznik, are you
17 aware that the DEA has, in fact, approved a
18 suspicious order monitoring system where
19 suspicious orders were to be reported after
20 the purchase was complete?

21 A. No.

22 Q. Okay. Would it surprise you
23 that the DEA has approved a suspicious order
24 monitoring system where suspicious orders
25 were to be reported after the purchase has

1 been complete?

2 MR. FINKELSTEIN: Object to
3 form.

4 THE WITNESS: Yeah.

5 (Prevoznik Exhibit 22 marked
6 for identification.)

7 QUESTIONS BY MR. MAHADY:

8 Q. Okay. I'm going to mark this
9 as Prevoznik 22.

10 Mr. Prevoznik, let me know when
11 you've had a chance to read this.

12 A. Okay.

13 Q. Okay.

14 MR. FARRELL: Before you do so,
15 I'm going to place an objection on the
16 record. This is correspondence dated
17 1998 between Bergen Brunswick
18 Corporation and the DEA, and the scope
19 of this document violates CMO 2, where
20 the defendants requested and the Court
21 granted a limitation with temporal
22 scope of discovery to 2006.

23 MR. MAHADY: This document was
24 produced to the DEA, was identified as
25 a document that Mr. Prevoznik reviewed

1 in preparing for his corporate
2 designee deposition today.

3 I will also note that the
4 plaintiffs spent a majority of their
5 questioning on issues that predate
6 2007, including using documentation
7 that was between DEA and other
8 registrants that was pre-2007.

9 SPECIAL MASTER COHEN: Just to
10 clarify, you said produced to the DEA.
11 Did you mean by the DEA?

12 MR. MAHADY: From the DEA.

13 QUESTIONS BY MR. MAHADY:

14 Q. Mr. Prevoznik, this morning
15 Mr. Farrell asked you questions about
16 documents that bear a US DEA Bates number,
17 correct?

18 A. Yes.

19 Q. All right. And those are
20 documents that the DEA has produced, correct?

21 A. Correct.

22 Q. Okay. And these were documents
23 that were in the custody and control of the
24 DEA, correct?

25 A. Yes.

1 Q. Okay. Have you seen this
2 document before?

3 A. Yes.

4 Q. When was the first time you saw
5 this document?

6 A. It was during my prep. I don't
7 have a specific date.

8 Q. Did you see -- so you've been
9 deposed on three separate days, correct?

10 A. Yes.

11 Q. And the first two days of your
12 deposition were, I believe, April 17th and
13 April 18th.

14 Did you see this document
15 before you were deposed on April 17th and
16 April 18th?

17 A. Yes.

18 Q. Okay. Are you aware that the
19 Department of Justice did not produce this
20 document until Tuesday of this week?

21 A. No.

22 Q. Okay.

23 MS. MAINIGI: I believe it got
24 to us Wednesday.

25 MR. MAHADY: Correction for the

1 record. It was Wednesday of this week
2 we received it.

3 MS. MAINIGI: Actually, it was
4 hand-delivered to Williams on Tuesday.

5 MR. MAHADY: Well, the point
6 isn't Tuesday or Wednesday, it's
7 that --

8 MR. FINKELSTEIN: No, it was
9 hand-delivered. So you knew you had
10 represented previously that it was
11 Federal Express'd, but it wasn't.

12 MR. MAHADY: Okay. Well,
13 the -- I would just like to --

14 MS. MAINIGI: That's what I
15 understood.

16 MR. FINKELSTEIN: And you were
17 wrong.

18 MR. MAHADY: -- note for the
19 record that this document was reviewed
20 by the witness in advance of the first
21 two days of his deposition and was
22 produced a month after the fact.

23 MR. FINKELSTEIN: And now you
24 have it. Go ahead and ask questions
25 about it.

1 MR. MAHADY: I will. Thank
2 you.

3 MR. FINKELSTEIN: You're
4 welcome.

5 QUESTIONS BY MR. MAHADY:

6 Q. Mr. Prevoznik, can you please
7 direct your attention to the bottom of this
8 document?

9 A. Yes.

10 Q. And before we get there, I'm
11 sorry, this document is dated what?

12 A. July 23, 1998.

13 Q. And this document was sent to,
14 while the name is redacted, the regulatory
15 compliance and security services of Bergen
16 Brunswig Corporation; is that correct?

17 A. Correct.

18 Q. And it's signed, or stamped, by
19 Patricia M. Good, chief liaison and policy
20 section; is that right?

21 A. Yes.

22 Q. Okay. Can you direct your
23 attention to the bottom of the page below the
24 section that has been redacted, and can you
25 please read for me the subject line?

1 A. "Approved suspicious order
2 monitoring system."

3 Q. Okay. Now, if you can please
4 read to me for the record the first sentence
5 of the letter after "dear."

6 A. "This is to grant approval of
7 your request to implement on a nationwide
8 basis your newly developed system to identify
9 and report suspicious orders for controlled
10 substances and regulated chemicals."

11 Q. Okay. Can you -- so as
12 required by the federal regulations, correct?

13 A. Oh, I'm sorry, yes.

14 Q. Okay. Can you read the next
15 sentence, please?

16 A. "DEA managers who have been
17 involved with the testing of the system have
18 relied -- have relayed their positive
19 opinions regarding its ability to provide
20 information in a fashion which is not only
21 useful overall but is also responsive to the
22 needs of individual DEA offices."

23 Q. Okay. And we can agree that
24 this is an explicit approval from the DEA of
25 a particular system, correct?

1 MR. FINKELSTEIN: Objection.

2 Mischaracterizes the document.

3 THE WITNESS: No, it's a --

4 it's a granting -- they asked could

5 they implement this on a nationwide --

6 their newly designed system. So it's

7 this particular registrant, Bergen

8 Brunswig, who developed their own

9 system and asked can we -- can we

10 apply this nationwide.

11 And we said, yes, you may apply

12 it nationwide.

13 QUESTIONS BY MR. MAHADY:

14 Q. Okay. So --

15 A. It's not approving the system.

16 MR. FINKELSTEIN: Let the

17 witness finish his answer.

18 MR. MAHADY: I appreciate that.

19 THE WITNESS: It's just

20 approving the fact that they can now

21 put it nationwide.

22 QUESTIONS BY MR. MAHADY:

23 Q. Okay. So notwithstanding the

24 fact that the subject line of the letter is,

25 "Subject: Approve suspicious order

1 monitoring system," the position of the DEA
2 is that this was not an approval of the
3 system; is that correct?

4 MR. FINKELSTEIN: Objection.

5 Argumentative. Asked and answered.

6 You can answer again.

7 THE WITNESS: Can you please
8 repeat it?

9 QUESTIONS BY MR. MAHADY:

10 Q. Notwithstanding the fact that
11 the subject line of this letter is "approve
12 suspicious order monitoring system," it is
13 the position of the DEA here today, 20-some
14 years later, that this was not an approval of
15 the actual program itself; is that correct?

16 MR. FINKELSTEIN: Same
17 objections.

18 THE WITNESS: Yeah, that's not
19 what the letter says. The letter says
20 we approve your request to implement
21 your system on a nationwide basis.

22 Your system, Bergen Brunswig system.

23 QUESTIONS BY MR. MAHADY:

24 Q. And do you know if that system
25 was developed in coordination with the DEA?

1 A. Well, it appears that we had
2 some input into it, so it's no different than
3 when I previously testified that you have --
4 the regulations require the registrant to
5 design. So this is designing it.

6 So when -- as I said earlier
7 today, when we go in to listen to the design
8 or what is the system that you're going to
9 implement, DEA is in listening mode, we will
10 make suggestions.

11 If we -- as we listen to it, we
12 will make suggestions: Oh, you may want to
13 think of this; you may want to think of that.

14 Q. Okay.

15 A. So then it jumps to the
16 operational side. So you now have the
17 design, but now you have to operate it. So
18 what is the operation, what was actually --
19 how did the system operate.

20 And that is the registrant
21 running that system, not DEA.

22 Q. Okay. So the DEA approved the
23 design of the system but not the operation;
24 is that what you're saying?

25 MR. FINKELSTEIN: Objection.

1 Mischaracterizes his prior testimony.

2 THE WITNESS: No, we said we
3 approve the request to implement the
4 system nationwide.

5 QUESTIONS BY MR. MAHADY:

6 Q. Okay. So in the eyes of DEA,
7 there's a distinction between approving the
8 system and approving the nationwide
9 implementation of a system.

10 Do I understand you correctly?

11 A. Well, I understand the request
12 seems to be that they asked, "Can we put this
13 nationwide?" and we said, "Yes, go ahead."

14 (Prevoznik Exhibit 23 marked
15 for identification.)

16 QUESTIONS BY MR. MAHADY:

17 Q. Okay. I'm going to mark the
18 next document as Prevoznik 23.

19 MR. FINKELSTEIN: Do you have a
20 copy for me?

21 MR. MAHADY: I do.

22 MR. FINKELSTEIN: Wait till I
23 get my copy before you answer
24 questions.

25 THE WITNESS: Sure.

1 MR. FARRELL: Again, for the
2 record, I'm going to place an
3 objection. This is not a document
4 produced by the DEA. This is a
5 document bearing the ABDC Bates number
6 in the bottom right-hand corner, a
7 document dated 1996.

8 The defendants argued for and
9 received an order preventing the
10 plaintiffs from conducting discovery
11 on DEA communications with the
12 wholesalers prior to 2006, and yet now
13 they're attempting to introduce
14 selected documents on the very subject
15 matter.

16 So we reserve our right to make
17 a request to the Court to allow us to
18 reopen discovery in this regard.

19 MR. MAHADY: Special Master
20 Cohen, this issue has been addressed
21 in e-mail correspondence to you this
22 week. I believe it -- the last
23 request from you was to plaintiffs
24 asking that this resolve the issue.
25 That was over two days ago. There was

1 no response.

2 So I'm going to ask you to
3 instruct Mr. Farrell, who is trying to
4 slow down and impede the questioning,
5 that he not continue to raise this
6 same issue with every document that's
7 introduced.

8 MR. FINKELSTEIN: I'll note
9 that we let them ask and we're letting
10 you ask, but it appears that you all
11 had a copy of what you were
12 complaining you didn't receive a copy
13 of for a long time, so...

14 MR. MAHADY: And I'll represent
15 to the Department of Justice that the
16 copy that the Department of Justice
17 produced is different in a material
18 way than the copy that was in the
19 possession of AmerisourceBergen.

20 QUESTIONS BY MR. MAHADY:

21 Q. Mr. Prevoznik, are you ready?

22 A. Yes.

23 Q. Okay.

24 MR. FARRELL: Hold on. Am I
25 being instructed not to lodge

1 objections?

2 SPECIAL MASTER COHEN: You
3 certainly can lodge an objection in
4 the same way that the defense were
5 objecting to questioning by the
6 plaintiffs.

7 What I suggest you do, though,
8 is find a which to say an objection in
9 five words or less.

10 MR. FARRELL: If I can have my
11 objections preserved for the record,
12 then I won't need to object at all.

13 SPECIAL MASTER COHEN: Will you
14 give him a continuing objection on
15 that basis?

16 MR. MAHADY: That's fine.

17 Can we go off the record?

18 VIDEOGRAPHER: Going off
19 record. The time is 1:57.

20 (Off the record at 1:57 p.m.)

21 VIDEOGRAPHER: We're going back
22 on the record.

23 MR. FINKELSTEIN: Go ahead,
24 back on the record.

25 VIDEOGRAPHER: Going back on

1 the record. Beginning of Media

2 File 6. Time is 1:58.

3 MR. FINKELSTEIN: Mr. Mahady,
4 you had represented that there were
5 significant differences. Do you want
6 to explain those? Because I have your
7 production right here, and the only
8 difference is it seems that you had an
9 unredacted version of this document.

10 MR. MAHADY: Sure,
11 Mr. Finkelstein. I'd just like to
12 start first with that it's not the
13 same document that I just made that
14 representation relating to. I was
15 referring to the 1998 letter.

16 In the copy of the document
17 that was produced by the Department of
18 Justice, there are redactions, and
19 redactions in areas of the document
20 where there is no text in the version
21 that was in the possession of
22 AmerisourceBergen.

23 I will also note that at the
24 bottom of the version that was
25 produced by the Department of Justice,

1 there is a subject line, a subject,
2 "approve suspicious order monitoring
3 system," which is material and
4 relevant.

5 I would also like to note for
6 the record that the version of the
7 documents that are in possession of
8 AmerisourceBergen were provided to the
9 Department of Justice yesterday
10 afternoon around one o'clock for
11 purposes of completeness and in
12 advance of today's deposition, and I
13 received no response from anyone at
14 the DOJ.

15 MR. FINKELSTEIN: So we had
16 fewer than 24 hours.

17 But what I'm seeing is two
18 letters dated July 23, 1998. One is
19 addressed to Chris Zimmerman; the
20 other is addressed to a redacted name.
21 One says, "Dear Mr. Zimmerman," the
22 other says, "redacted." In every
23 other respect, apart from the
24 redactions and the subject, they
25 appear to be identical.

1 I think you have three hours to
2 ask the witness about the redacted
3 draft.

4 MR. MAHADY: And I think we're
5 talking about the document from
6 September 30, 1996, that's before the
7 witness.

8 QUESTIONS BY MR. MAHADY:

9 Q. Mr. Prevoznik, can you please
10 read the first paragraph of this letter --
11 before we get there.

12 Thomas Gitchel. Thomas Gitchel
13 is identified as the chief liaison and policy
14 section of the DEA, correct?

15 A. Correct.

16 Q. And he held that position in
17 1996?

18 A. Yes.

19 Q. Now, if a registrant has
20 questions about the regulation or the DEA's
21 interpretation of the regulations, those
22 questions are directed to the liaison and
23 policy section of the DEA, correct?

24 A. Correct.

25 Q. And is the chief the

1 highest-ranking member of that section?

2 A. Yes.

3 Q. Okay. This letter dated
4 September 30, 1996, to Thomas Gitchel was
5 sent by Chris Zimmerman of Bergen Brunswig.

6 Do you know Chris Zimmerman?

7 A. I know the name.

8 Q. Okay.

9 A. I don't know if we've ever met.

10 Q. Okay. I want to start -- and
11 I'll actually read the first paragraph for
12 purposes of time.

13 "The purposes of this letter is
14 to introduce the Drug Enforcement
15 Administration to an innovative new system
16 under development by Bergen Brunswig Drug
17 Company to monitor and report customer orders
18 of controlled substances which fit the
19 suspicious order criteria outlined in 21 CFR
20 1301.74(b)."

21 Did I read that correctly?

22 A. Yes.

23 Q. Okay. And that is the section
24 that we've been discussing today, right?

25 A. Yes.

1 Q. Okay. And that's the section
2 that governs the reporting of suspicious
3 orders?

4 A. Yes.

5 Q. Okay. Beginning with the next
6 sentence, "By way of background, as you know,
7 BBDC participated in the development of a
8 model excessive purchase report now in use by
9 many distributor registrants."

10 Were you aware that there was a
11 model excessive purchase report that was
12 being used by the registrants?

13 A. A model? Yes.

14 Q. Okay. It says, "As used by
15 BBDC, the excessive purchase report lists
16 total customer purchases for the reported
17 month which exceed predetermined multiples of
18 the average monthly purchase of BBDC's total
19 customer base."

20 Did I read that correctly?

21 A. Yes.

22 Q. Okay. So in describing the
23 model excessive purchase report, it refers to
24 customer purchases, correct?

25 A. Yes.

1 Q. And a monthly report, correct?

2 A. Correct.

3 Q. Okay. And it goes on to say at
4 the end of that paragraph, "This report is
5 produced in hard copy form monthly and is
6 sent via certified mail to each DEA field
7 office having responsibility for the
8 reporting BBDC locations."

9 Did I read that correctly?

10 A. Yes, you did.

11 Q. And is that your understanding
12 of how it worked?

13 A. Yes.

14 MR. FINKELSTEIN: Wait. Hang
15 on. Give me time to object.

16 THE WITNESS: I'm sorry.

17 MR. FINKELSTEIN: Objection.

18 Scope.

19 QUESTIONS BY MR. MAHADY:

20 Q. Next paragraph. "While
21 feedback from DEA users over the years has
22 generally confirmed our belief that the
23 report standing alone is a useful law
24 enforcement tool, BBDC suspicious order
25 compliance program also involves the

1 telephonic reporting of customer orders to
2 DEA."

3 Now, is it your understanding
4 that DEA users did consider the excess
5 purchase reports to be a useful law
6 enforcement tool?

7 A. Yes.

8 Q. Okay. And is it your
9 understanding that distributors like Bergen
10 Brunswig also placed telephonic report --
11 also performed telephonic reporting to the
12 DEA for suspicious orders in the '90s?

13 A. Yes, that's my understanding.

14 Q. Okay. And it goes on to say
15 that "in an average year, BBDC logs over
16 12,000 telephone calls to DEA field offices
17 nationwide to quarterly customer orders of
18 controlled substances which it believes could
19 fit the suspicious order criteria set forth
20 in 1301.74(b)."

21 Did I read that correctly?

22 A. Yes.

23 Q. And you have no reason to
24 dispute the fact stated here that Bergen
25 Brunswig was placing 12,000 calls to DEA

1 field offices a year, do you?

2 MR. FINKELSTEIN: Objection.

3 Scope.

4 THE WITNESS: No, I don't.

5 QUESTIONS BY MR. MAHADY:

6 Q. Okay. And then it goes on to
7 say that "In nearly every instance, the
8 telephonic contacts are made to report orders
9 which later appeared on the month end
10 excessive reports sent to DEA."

11 Did I read that correctly?

12 A. Yes.

13 Q. Okay. So the orders that were
14 being reported to the DEA daily,
15 telephonically, were also being included on
16 the month-end excessive purchase reports,
17 correct?

18 MR. FINKELSTEIN: Objection.

19 Scope.

20 THE WITNESS: That's what it
21 says.

22 QUESTIONS BY MR. MAHADY:

23 Q. Okay. Was that your
24 understanding?

25 MR. FINKELSTEIN: Scope.

1 THE WITNESS: Based on this,
2 yes, that's my understanding.

3 QUESTIONS BY MR. MAHADY:

4 Q. Okay. Now, next paragraph,
5 second sentence, "Some field offices have
6 insisted that BBDC not telephonically report
7 suspicious orders at all" --

8 MR. FINKELSTEIN: Where are
9 you?

10 MR. MAHADY: Bottom of the
11 page.

12 QUESTIONS BY MR. MAHADY:

13 Q. -- "but rather to mail or fax
14 copies of the order documents, 222 forms or
15 invoices of them instead."

16 Did I read that correctly?

17 A. Yes.

18 Q. Okay. So a DEA field office
19 could give guidance to registrants about how
20 they wanted suspicious orders reported,
21 correct?

22 MR. FINKELSTEIN: Scope.

23 THE WITNESS: Yes.

24 QUESTIONS BY MR. MAHADY:

25 Q. Okay. And your --

1 MS. MAINIGI: If I could
2 interrupt, why is that scope?

3 MR. FINKELSTEIN: Because the
4 authorization letter is explicit that
5 he is authorized to testify about
6 industrywide guidance but not
7 individual communications to specific
8 registrants.

9 MS. MAINIGI: Okay. Well, I
10 think that's industrywide, but thank
11 you for that clarification.

12 MR. FINKELSTEIN: Specific
13 phone calls to Bergen Brunswig is
14 industrywide?

15 MS. MAINIGI: I don't think
16 that's the scope of the question, but
17 I'll -- I apologize for interrupting.
18 I just wanted to know the answer.

19 MR. FINKELSTEIN: Do you
20 understand my objection?

21 THE WITNESS: Yeah.

22 MR. FINKELSTEIN: Okay.

23 QUESTIONS BY MR. MAHADY:

24 Q. So just to go back.

25 DEA field offices could provide

1 guidance to registrants about the suspicious
2 order reporting requirements, correct?

3 MR. FINKELSTEIN: Scope.

4 THE WITNESS: Yes.

5 QUESTIONS BY MR. MAHADY:

6 Q. Okay. And the DEA's
7 expectation would be that the registrants
8 listened to the guidance they were receiving
9 from the field offices, correct?

10 A. Yes.

11 Q. Okay. And if a DEA field
12 office told to -- advised a registrant to
13 report a suspicious order in one form versus
14 another, they should listen to that DEA field
15 office, correct?

16 A. Yes.

17 Q. Okay.

18 A. Yes.

19 Q. Now, the next sentence there,
20 it says, "Some offices have diplomatically
21 attempted to offer guidance as to the types
22 of orders that their offices would deem
23 reportable in an effort to limit the number
24 of telephone contacts."

25 Did I read that correctly?

1 A. Yes.

2 Q. Are you aware that some DEA
3 field offices in the '90s were trying to
4 limit the number of suspicious orders being
5 reported telephonically by the registrants?

6 MR. FINKELSTEIN: Foundation.
7 Exceeds the scope of the Touhy
8 authorization.

9 You can answer in your personal
10 capacity.

11 THE WITNESS: I'm not
12 personally aware of that.

13 QUESTIONS BY MR. MAHADY:

14 Q. Okay. But you have no reason
15 to dispute the accuracy of that statement?

16 MR. FINKELSTEIN: Scope. Calls
17 for speculation.

18 You can answer.

19 THE WITNESS: I don't.

20 QUESTIONS BY MR. MAHADY:

21 Q. Okay. I want to go down to the
22 middle of the page where it says, "Against
23 this backdrop."

24 Do you see it?

25 A. Yes.

1 Q. Okay. "Against this backdrop,
2 BBDC set to work on the development of a
3 suspicious order reporting system that would
4 provide better quality information to DEA in
5 a more efficient manner."

6 Did I read that correctly?

7 A. Yes.

8 Q. And you would agree with me
9 that that's a laudable goal to have for a
10 registrant?

11 A. A lot of what?

12 Q. That's something that a
13 registrant should strive to do, is to provide
14 better quality information to the DEA?

15 A. Yes.

16 Q. Okay. Now, I'm going to read
17 the next paragraph, which describes the plan.

18 "Our plan involves the creation
19 of a computer program that compares a
20 customer's controlled substance orders
21 expressed in metric units of the active
22 ingredient against a standard representing an
23 average of the customer's prior four months
24 of orders. Customers whose order exceed by a
25 specified percentage their prior four-month

1 average order history would be printed on a
2 summary report."

3 Did I read that correctly?

4 A. Yes.

5 Q. Okay. "BBDC's mainframe
6 computer in Orange, California, would
7 automatically fax this report simultaneously
8 to each respective DEA field office daily in
9 the early a.m. hours after the distribution
10 center has completed order processing
11 activities."

12 Did I read that correctly?

13 A. Yes.

14 Q. Okay. So what's contemplated
15 here is that BBDC would generate a report at
16 the end of the night, after it had completed
17 its order processing for the day, correct?

18 MR. FINKELSTEIN: Objection.

19 Scope. Calls for speculation.

20 THE WITNESS: So they pulled --
21 so the orders were already pulled and
22 already ready to ship?

23 QUESTIONS BY MR. MAHADY:

24 Q. Yes. Okay.

25 MR. FINKELSTEIN: Scope. Calls

1 for speculation.

2 You can answer.

3 QUESTIONS BY MR. MAHADY:

4 Q. "When DEA offices open each
5 day, the summary report would be waiting for
6 their review. DEA offices could also elect
7 to receive a month-end version of this report
8 via US mail. The summary report would show
9 the customer name, address, DEA number, item
10 description, NDC number, order date, active
11 ingredient volume ordered, active ingredient
12 shipped and customer allowance, i.e., average
13 of customer's prior four-month orders."

14 Did I read that correctly?

15 A. Yes.

16 Q. Now, what's contemplated here
17 in the summary report that would be faxed
18 daily to the DEA, so the DEA field offices
19 would have it in the morning, included active
20 ingredient shipped, correct?

21 MR. FINKELSTEIN: Scope. Calls
22 for speculation.

23 THE WITNESS: It's what it
24 says.

25

1 QUESTIONS BY MR. MAHADY:

2 Q. Okay.

3 A. But again, these are all
4 after-the-fact shipping.

5 Q. Correct.

6 So these would be suspicious
7 orders that were reported to the DEA after
8 they had already been shipped, right?

9 A. Right.

10 MR. FINKELSTEIN: Wait.

11 THE WITNESS: I'm sorry.

12 MR. FINKELSTEIN: Calls for
13 speculation.

14 QUESTIONS BY MR. MAHADY:

15 Q. And Bergen Brunswig is seeking
16 to implement a program that would do just
17 that, report -- I'm sorry, ship and then
18 report suspicious orders, right?

19 MR. FINKELSTEIN: Scope. Calls
20 for speculation.

21 THE WITNESS: But in -- as this
22 morning's testimony, in all these
23 various communications we have stated
24 that a suspicious order is prior to
25 shipment.

1 QUESTIONS BY MR. MAHADY:

2 Q. Okay.

3 A. So you're giving us, again,
4 after the fact, which does not -- just
5 because you report it doesn't alleviate that
6 you maintain effective controls over
7 diversion.

8 Q. Okay. But Bergen Brunswig is
9 specifically saying, "We're going to report
10 suspicious orders after they had already been
11 shipped," correct?

12 MR. FINKELSTEIN: Scope. Calls
13 for speculation.

14 You can answer in your personal
15 capacity.

16 QUESTIONS BY MR. MAHADY:

17 Q. That's what they're proposing
18 to implement. That's all I'm trying to ask
19 you based off of this document.

20 A. Right, and --

21 MR. FINKELSTEIN: You can
22 answer based on your personal
23 understanding of what Bergen Brunswig
24 is proposing to implement.

25 QUESTIONS BY MR. MAHADY:

1 Q. Okay. And your answer was
2 "right," that's your understanding of what
3 they're proposing?

4 A. That's my understanding of it,
5 yes.

6 Q. Okay. Next page. "Our intent
7 is to receive DEA's permission to replace our
8 current manner of daily suspicious order
9 reporting with the daily electronic facsimile
10 report," correct?

11 A. Yes.

12 Q. Okay. "We would like to have
13 DEA input on the final product because DEA
14 will be the primary users. One suggestion
15 would be to coordinate with one of your field
16 offices, perhaps the Los Angeles office, to
17 meet with our project development team."

18 Did I read that correctly?

19 A. Yes.

20 Q. Okay. It goes on to
21 say, "While your field office could beta test
22 the report and provide us with input on
23 aesthetics and content, there are some key
24 questions that DEA would need to provide
25 input on before the report is finalized. One

1 question would be the assigned -- assignment
2 of the percentage value that a customer's
3 order would have to exceed before that order
4 would appear on the report."

5 Did I read that correctly?

6 A. Yes.

7 Q. Okay. And then it goes on to
8 say, "Tom, we are excited about the
9 opportunity to make constructive changes in
10 our suspicious order reporting system. By
11 working in a partnership with your office, we
12 can perhaps lead the way to developing a new
13 system that everyone feels good about."

14 Did I read that correctly?

15 A. Yes.

16 Q. Okay. And as the
17 representative from the DEA, was it your
18 understanding that Bergen Brunswig in 1996
19 was trying to work with the DEA as part of a
20 partnership to develop a system that everyone
21 could feel good about?

22 MR. FINKELSTEIN: Scope. Calls
23 for speculation.

24 You, Tom Prevoznik, can answer.

25 THE WITNESS: Yes, that's what

1 it appears to be.

2 (Prevoznik Exhibit 26 marked
3 for identification.)

4 QUESTIONS BY MR. MAHADY:

5 Q. Okay. I'm going to mark P,
6 Prevoznik 24 {sic}.

7 Okay. And there is a back.

8 A. Okay. Thank you.

9 Q. Okay. Again, this document has
10 a US DEA Bates number; is that correct?

11 A. Yes.

12 Q. All right. So this document
13 was in the possession, custody and control of
14 the United States DEA, correct?

15 A. Correct.

16 MR. FINKELSTEIN: And appears
17 to be identical to ABDC269353.

18 MR. MAHADY: And I did not say
19 it wasn't.

20 MR. FINKELSTEIN: Progress.

21 QUESTIONS BY MR. MAHADY:

22 Q. This document is dated
23 October 29, 1996, right?

24 A. It looks like 1996.

25 Q. Yeah, the stamp is really not

1 the best.

2 A. Yeah, it's a little hard to
3 say, but, yeah, it looks like 1996.

4 Q. Okay. And that's just under
5 one month after Mr. Zimmerman sent his letter
6 describing the proposed program to Thomas
7 Gitchel; is that right?

8 A. Yes.

9 Q. Okay. And in the first
10 paragraph of this letter which is sent to
11 Bergen Brunswig from Mr. Gitchel, he said
12 that "reference is made to your recent letter
13 in which you requested that Bergen Brunswig
14 be permitted to replace its current
15 telephonic reporting of suspicious orders
16 with a daily report transmitted by
17 facsimile."

18 Did I read that correctly?

19 A. Yes.

20 Q. Okay. So the DEA understood
21 that Bergen Brunswig was trying to replace
22 its daily suspicious order reporting with
23 this summary fax, right?

24 MR. FINKELSTEIN: Objection to
25 the characterization.

1 THE WITNESS: It looks like --
2 yes, so that's what it looks like, but
3 it -- because it's a daily report of
4 sales that have been commenced, it
5 would be the excessive purchase
6 reports.

7 QUESTIONS BY MR. MAHADY:

8 Q. Okay. But they're specifically
9 referring to suspicious orders?

10 A. I see that's what -- what
11 they're saying, but I'm just -- I'm telling
12 you that we've already shown and have been
13 clear that suspicious orders are prior to
14 shipment.

15 So you're giving us a -- in
16 reading this, you're giving us after-the-fact
17 purchase reports, and that was --

18 Q. Okay. So would -- I'm sorry.

19 A. And that was part -- and we at
20 DEA at this time in particular, 1996, where
21 ARCOS was at least 9 to 12 months not being
22 accurate or being caught up to speed, this
23 was -- this was a very good tool for us
24 because it was more up-to-date information
25 than we would have if we waited the 9 or 12

1 months for ARCOS data to catch up.

2 Q. Okay.

3 A. To catch up. So...

4 Q. But at least Bergen Brunswig
5 was saying to the DEA these are suspicious
6 orders that we're reporting, correct?

7 A. That's what it says, yes.

8 Q. Okay. So your expectation
9 would be that the DEA would have corrected
10 them and said, no, you certainly can't be
11 referring to suspicious orders if you're
12 referring to after-the-fact sales; is that
13 right?

14 MR. FINKELSTEIN: Objection.
15 Mischaracterizes. Calls for
16 speculation.

17 THE WITNESS: I'm sorry, can
18 you repeat that?

19 QUESTIONS BY MR. MAHADY:

20 Q. Bergen Brunswig was developing
21 a program to meet with their suspicious order
22 reporting requirements, correct?

23 MR. FINKELSTEIN: Objection.
24 Scope. Calls for speculation.

25

1 QUESTIONS BY MR. MAHADY:

2 Q. That's what these letters are
3 about?

4 A. Well, I mean, it started with
5 an excessive -- we started with an excessive
6 purchase model, and now you jumped to
7 suspicious orders, so --

8 Q. Right.

9 So there was a reference in the
10 last document to excessive purchase reports?

11 A. Right, which are -- which are
12 after the fact.

13 Q. After the fact.

14 A. Right.

15 Q. And this new fax system is to
16 replace the daily phone calls.

17 Are we on the same page?

18 A. Right.

19 Q. Okay. And the daily phone
20 calls were to report suspicious orders,
21 correct?

22 A. Okay.

23 Q. Okay. And these faxes are to
24 report suspicious orders as well, as
25 represented by Bergen Brunswig?

1 MR. FINKELSTEIN: Objection.

2 Foundation.

3 THE WITNESS: Well, it's a
4 little confusing because you're saying
5 that you're going to pull the orders
6 and then you're going to fax the
7 summaries to us after the fact.

8 QUESTIONS BY MR. MAHADY:

9 Q. Well, let's look at the DEA's
10 response.

11 A. Right?

12 Q. Let's look at the DEA's
13 response. This is from the DEA. "Reference
14 is made to your recent letter in which you
15 requested that Bergen Brunswig be permitted
16 to replace its current telephonic reporting
17 of suspicious orders with a daily report
18 transmitted by facsimile."

19 Okay? So the DEA is saying
20 your request is to report your daily
21 suspicious order reporting, correct?

22 A. Correct.

23 Q. Okay. The DEA goes on to say,
24 "We have reviewed your proposal and feel that
25 it could be a viable alternative to the

1 current system. It is our understanding that
2 a computer program has been created that can
3 compare a customer's controlled substances
4 orders to an average of the customer's order
5 for the prior four months. Customer orders
6 that exceed their four-month average order
7 history by an as-yet unspecified percentage
8 would be shown on a summary report that would
9 be sent to the appropriate DEA field office
10 on a daily basis."

11 Did I read that correctly?

12 A. Yes.

13 Q. Okay. And they are talking
14 here about suspicious orders, correct?

15 MR. FINKELSTEIN: Objection.

16 Scope. Mischaracterizes.

17 THE WITNESS: Well, no. If you
18 keep going, it gets down to a reading
19 of both ordered and shipped. So
20 they're indicating it's after the
21 fact.

22 QUESTIONS BY MR. MAHADY:

23 Q. Right.

24

25

1 A. So it wouldn't be a suspicious
2 order. It would be an excessive purchase.

3 Q. Okay. Let's keep reading.

4 A. It's an after-the-fact
5 purchase.

6 Q. "As proposed, the summary
7 report would include the customer's name,
8 address and DEA number, a description of the
9 item ordered, the NDC number, date ordered,
10 active ingredient volume ordered and shipped,
11 and the customer's allowance on average -- or
12 average order."

13 Did I read that correctly?

14 A. Yes.

15 Q. Okay. And what the DEA is
16 saying is that we understand that you want to
17 replace your daily suspicious order reporting
18 with a summary fax that would include, among
19 other information, the amount of product that
20 was shipped.

21 A. Right. So they're reporting
22 excessive -- they're doing an excess purchase
23 report, is what they're doing.

24 Q. Okay. Now, do you see anywhere
25 in the first two paragraphs where the DEA

1 clarifies that what you are proposing Bergen
2 Brunswig is an excessive purchase reporting
3 system, not a suspicious order reporting
4 system?

5 A. No, I don't.

6 Q. Okay. They -- the DEA says
7 suspicious order, right?

8 MR. FINKELSTEIN: Objection.
9 Mischaracterizes the document.

10 QUESTIONS BY MR. MAHADY:

11 Q. The first sentence.

12 A. Yes, it's reference to your
13 letter.

14 Q. Suspicious order?

15 A. Yeah.

16 Q. Okay. Now, these excessive
17 purchase reports, just because we've talked
18 about them in the last document, you just
19 brought them up, the DEA understood that
20 these were also suspicious order reports,
21 right?

22 A. No, because they were after the
23 fact.

24 Q. Okay. So the DEA did not
25 understand that the monthly reports were

1 suspicious order reports?

2 A. Well, I can just tell you
3 what D -- DEA policy has been not to approve
4 a system. It has also been that a suspicious
5 order is prior to shipment.

6 Q. Is it possible that the DEA
7 deviated from their policy?

8 MR. FINKELSTEIN: Objection.
9 Calls for speculation.

10 THE WITNESS: I can just tell
11 you what the policy is of DEA.

12 QUESTIONS BY MR. MAHADY:

13 Q. I appreciate that.
14 Is it possible that they
15 deviated from their policy?

16 MR. FINKELSTEIN: Calls for
17 speculation.

18 THE WITNESS: Anything is
19 possible.

20 QUESTIONS BY MR. MAHADY:

21 Q. Okay. And it's possible that
22 they deviated from their policy in approving
23 for implementation nationwide a suspicious
24 order monitoring system that reported
25 suspicious orders after the order had already

1 been shipped?

2 MR. FINKELSTEIN: Calls for
3 speculation.

4 THE WITNESS: Can you please
5 repeat it?

6 MR. MAHADY: Can you read that
7 back? Because I probably can't do it
8 as well the second time.

9 (Court Reporter read back
10 question.)

11 MR. FINKELSTEIN: Calls for
12 speculation and mischaracterizes the
13 document.

14 You can answer.

15 THE WITNESS: Yeah, I don't
16 know.

17 QUESTIONS BY MR. MAHADY:

18 Q. It's possible?

19 MR. FINKELSTEIN: Calls for
20 speculation.

21 THE WITNESS: It's possible.

22 QUESTIONS BY MR. MAHADY:

23 Q. Okay. Now, the next -- the
24 third paragraph. "We note that unlike the
25 program that generates Bergen Brunswig's

1 monthly suspicious order report, the new
2 program will compare the customer's order to
3 his or her previous orders rather than to
4 orders placed by other customers."

5 Did I read that correctly?

6 A. Yes.

7 Q. Now, the DEA is the one
8 referring to the monthly report as a
9 suspicious order report, correct?

10 A. Yes.

11 Q. Okay. So at least some
12 individuals at the DEA understood the monthly
13 report of after-the-fact sales to be
14 suspicious order reports, based off of this
15 document?

16 MR. FINKELSTEIN: Calls for
17 speculation.

18 THE WITNESS: I don't know. I
19 mean, it -- I think at this time
20 excessive purchase and suspicious
21 orders were sometimes understood as
22 one or the other, but clearly a
23 suspicious order that we have been
24 clear on, the suspicious order was not
25 to be -- was prior to shipment.

1 So summary reports, if -- any
2 summary report that showed sales that
3 were commenced and done were
4 considered excessive purchase orders.
5 They were not suspicious orders,
6 because suspicious orders would be
7 before the shipment.

8 QUESTIONS BY MR. MAHADY:

9 Q. That's not in the regulation,
10 correct?

11 MR. FINKELSTEIN: Objection.

12 Argumentative. Mischaracterizes the
13 regulation.

14 QUESTIONS BY MR. MAHADY:

15 Q. Does the regulation say that a
16 suspicious order needs to be reported prior
17 to shipment?

18 A. It says immediately upon
19 discovery.

20 Q. Okay.

21 A. And the statute says you
22 have -- that each registrant is to maintain
23 effective controls of that.

24 Q. I appreciate that.

25 But very specifically, does

1 the registrate -- does the statute or the
2 implementing regulations say that a
3 suspicious order must be reported prior to
4 shipment?

5 MR. FINKELSTEIN: Asked and
6 answered.

7 MR. MAHADY: I don't believe he
8 answered the question, that specific
9 question.

10 MR. FINKELSTEIN: I believe he
11 did.

12 You can answer again.

13 THE WITNESS: I thought I did,
14 too.

15 The statute requires to have
16 effective control to guard against
17 diversion.

18 QUESTIONS BY MR. MAHADY:

19 Q. I appreciate that.

20 A. So if you have a suspicious
21 order, which is prior to shipping, you have a
22 reason or reason to believe that that -- that
23 is going to be diverted into the illicit
24 market, right? So your system is designed to
25 give -- to find that reason or reasons why

1 this shipment -- or why this order is to be
2 suspicious. That is prior to shipping.

3 Q. Okay.

4 A. So in order to maintain
5 effective controls, you would then have to
6 look at the suspicion. What triggered the
7 suspicion -- we're in Bergen Brunswig. Let's
8 go with Bergen. What triggered Bergen to
9 say, "Wait a minute, something's not right
10 with this order."

11 Q. Okay.

12 A. So then they should halt and
13 try to figure out, what can we alleviate
14 that.

15 Q. Okay.

16 A. What can we alleviate to that
17 suspicion.

18 So if you're just giving us
19 summary reports at the end where we've
20 already shipped it and say, "these are all
21 suspicious orders," well, what did you -- how
22 did you maintain any effective controls?
23 That would be my question.

24 Q. Okay. I have a very specific
25 question --

1 A. Sure.

2 Q. -- and I'm just talking about
3 the text of the regulations. Okay?

4 Does the text of the
5 regulations contain anything that explicitly
6 says that a suspicious order must be reported
7 to the DEA prior to shipment?

8 A. No, it says immediately upon
9 discovery.

10 Q. Okay. Now --

11 MR. FINKELSTEIN: Counsel, I'm
12 going to ask for a break in five
13 minutes.

14 MR. MAHADY: Sure.

15 QUESTIONS BY MR. MAHADY:

16 Q. Tom Gitchel, okay, he's the one
17 that wrote this letter, right?

18 A. Yes.

19 Q. And at least to Tom Gitchel,
20 Bergen Brunswig's monthly report was a
21 suspicious order report?

22 MR. FINKELSTEIN: Calls for
23 speculation. Scope.

24 THE WITNESS: I'm not sure what
25 Tom -- yeah.

1 QUESTIONS BY MR. MAHADY:

2 Q. But Tom refers to it as a
3 monthly suspicious order report, correct?

4 A. Right.

5 Q. All right. And at least to Tom
6 Gitchel, his understanding of what was being
7 proposed is a daily fax of suspicious orders
8 that would include, among other information,
9 the amount that was shipped, correct?

10 A. Correct.

11 MR. FINKELSTEIN: Scope. Calls
12 for speculation.

13 QUESTIONS BY MR. MAHADY:

14 Q. Now, if you can turn to the
15 next page, last paragraph, "We look forward
16 to working with you on this new project which
17 we, too, hope will lead to a more efficient
18 suspicious order reporting system."

19 Did I read that correctly?

20 A. Yes.

21 Q. Now, they clearly were
22 developing a suspicious order reporting
23 system, right?

24 MR. FINKELSTEIN: Objection.

25 Vague. Scope. Calls for speculation.

1 THE WITNESS: Again, I can only
2 reiterate what the DEA policy is.
3 Suspicious orders are prior to
4 shipment.

5 QUESTIONS BY MR. MAHADY:

6 Q. But you're here on behalf of
7 the DEA and registrant that was provided --
8 or guidance that was provided to registrants.

9 Tom Gitchel was the chief
10 liaison -- the chief of the liaison and
11 policy section, right?

12 A. Yes.

13 Q. He's not some low-level DEA
14 employee, right?

15 A. No.

16 Q. He's pretty high up?

17 A. Yes.

18 Q. Okay. And his section was the
19 one that was responsible for interpreting the
20 regulations, correct?

21 MR. FINKELSTEIN: Objection.

22 Scope. Foundation.

23 You can answer.

24 THE WITNESS: Yes.

25

1 QUESTIONS BY MR. MAHADY:

2 Q. And at least to Tom Gitchel,
3 the monthly reports, the monthly excessive
4 purchase reports, were suspicious order
5 reports, correct?

6 MR. FINKELSTEIN: Objection.
7 Scope. Calls for speculation. Asked
8 and answered.

9 THE WITNESS: We've also read
10 letters --

11 QUESTIONS BY MR. MAHADY:

12 Q. Mr. Prevoznik --

13 A. I'm just telling you that
14 Mr. Gitchel also wrote letters that we went
15 through this morning that also said what I
16 had said the DEA's policy is.

17 Q. Okay.

18 A. It's after the shipment --
19 suspicious orders prior to shipment.

20 Q. So was Mr. Gitchel giving
21 inconsistent guidance to the registrants, in
22 your opinion?

23 MR. FINKELSTEIN: Scope.

24 You can give your opinion.

25 THE WITNESS: Slightly, yes.

1 MR. MAHADY: Okay. We can take
2 a break.

3 VIDEOGRAPHER: We're going off
4 record. The time is 2:32.

5 (Off the record at 2:32 p.m.)

6 VIDEOGRAPHER: We're going back
7 on record. Beginning of Media File
8 Number 7. The time is 2:45.

9 QUESTIONS BY MR. MAHADY:

10 Q. All right. Mr. Prevoznik,
11 sticking with Exhibit Prevoznik 24 for just
12 one more question or two.

13 Turning back to the first page
14 of that document from Mr. Gitchel to
15 Mr. Zimmerman at Bergen Brunswig, it says
16 that -- Mr. Gitchel said, "We agree that it
17 would be prudent to test this new program
18 before instituting it nationwide and concur
19 with your suggestion to use the DEA Los
20 Angeles division office for the beta test."

21 Did I read that correct?

22 A. Yes.

23 Q. All right. And it says, "We
24 would appreciate it if you could postpone
25 starting the testing until after February 1,

1 1997, as Ms. Betsy Willis, who has been
2 selected for the diversion program manager
3 position in the Los Angeles field division,
4 will not be reporting for duty until the end
5 of January."

6 Did I read that correctly?

7 A. Yes.

8 Q. All right. And in preparing
9 for your deposition today, did you have the
10 opportunity to speak with Ms. Betsy Willis?

11 A. No, I did not.

12 Q. I would like to mark Prevoznik
13 25.

14 (Prevoznik Exhibit 25 marked
15 for identification.)

16 QUESTIONS BY MR. MAHADY:

17 Q. For the record, while the
18 witness has an opportunity to read the
19 document, the Bates number is
20 ABDCMDL00269350.

21 It's a letter from Chris
22 Zimmerman to Thomas Gitchel, chief liaison
23 and policy section, US DEA, December 30,
24 1997.

25 A. Okay.

1 Q. Okay. Let's start with the
2 first paragraph of the letter from
3 Mr. Zimmerman to Mr. Gitchel.

4 "This letter serves as a follow
5 up to previous written correspondence, copy
6 enclosed, and telephone conversations
7 between -- Bergen Brunswig Drug Company has
8 had with the DEA pertaining to BBDC's newly
9 developed system to monitor and report
10 customer orders of controlled substances
11 which fit the suspicious order criteria
12 outlined in 21 CFR 1301.74(b)."

13 Did I read that correctly?

14 A. Yes.

15 Q. Okay. So this correspondence
16 relates to Bergen Brunswig's development of a
17 new suspicious order monitoring system to
18 meet the requirements of 21 CFR 1301.74(b),
19 correct?

20 MR. FINKELSTEIN: Scope.

21 THE WITNESS: Yes.

22 QUESTIONS BY MR. MAHADY:

23 Q. Okay. Next paragraph. "The
24 system is clearly described in the enclosed
25 September 30, 1996 correspondence. Per your

1 instruction, BBDC began beta testing the new
2 suspicious order reporting system with the
3 DEA Los Angeles field office in March 1997.
4 Our BBDC Valencia division began the new
5 suspicious order reporting to the LA DEA
6 office in March 1, 1997; BBDC Corona division
7 began the new reporting to the Riverside DEA
8 office on April 1, 1997; and BBDC Hawaii
9 began this new reporting to the LA DEA office
10 on May 1, 1997; and BBDC Orlando began the
11 new reporting to the Tampa DEA office on
12 June 1, 1997. All BBDC test divisions are
13 currently reporting suspicious orders to DEA
14 via the automated fax function of the new
15 reporting system."

16 Did I read that correctly?

17 A. Yes.

18 Q. Okay. And in preparing for
19 your testimony today, did you speak with
20 anyone who was at the Los Angeles field
21 office in 1997?

22 A. No.

23 Q. In preparing for your testimony
24 today, did you speak with anyone who was at
25 the Riverside DEA office on April 1, 1997?

1 A. I don't believe so.

2 Q. Okay. And what about anyone
3 who was at the Tampa DEA office in June
4 of 1997?

5 A. I'm trying to remember where
6 everybody was. I'm not sure.

7 Q. Okay. Did you speak with
8 anyone who was involved -- anyone at the DEA
9 who was involved in the development and
10 testing of the Bergen Brunswick suspicious
11 order monitoring system in 1990 -- between
12 1996 and 1998, to your knowledge?

13 A. Not to my knowledge.

14 Q. Okay. The next paragraph. "We
15 have had several conversations/meetings with
16 Ms. Betsy Willis, DEA diversion program
17 manager; Ms. Valencia Abrams, DEA Los Angeles
18 division group supervisor; Mr. Thomas Cox,
19 DEA Riverside diversion group supervisor; and
20 Mr. Arthur Fierman-Rentas, DEA Tampa
21 diversion group supervisor. All DEA
22 personnel currently involved with the beta
23 test program have been very pleased, and
24 Ms. Willis has given BBDC permission to
25 discontinue the submission of monthly ARCOS

1 suspicious order report, parens, variance
2 report, to DEA for the BBDC Corona, Valencia
3 and Hawaii divisions. Correspondence
4 enclosed."

5 Sitting here today, you have no
6 reason to dispute that all the individuals
7 involved with the testing were very pleased
8 with the suspicious order monitoring program
9 being developed?

10 A. I have no idea.

11 MR. FINKELSTEIN: Wait. Scope.
12 Calls for speculation.

13 You can answer in your personal
14 capacity.

15 THE WITNESS: I have no idea.

16 QUESTIONS BY MR. MAHADY:

17 Q. It goes on to say at the end of
18 the page, "BBDC has approached other DEA
19 field offices regarding the implementation
20 and beta testing of our new suspicious order
21 reporting system. However, those DEA field
22 offices have indicated that they would not
23 implement the new reporting system until they
24 received direction from Washington, DC."

25 Did I read that correctly?

1 A. Yes.

2 Q. Top of the next page. "BBDC
3 has already made several changes to our
4 proposed new reporting system at the
5 direction of the DEA field offices in whose
6 jurisdiction it is being tested. It has been
7 an extremely positive experience working
8 closely with DEA to develop a suspicious
9 order reporting system that benefits both the
10 wholesaler and the DEA."

11 Did I read that correctly?

12 A. Yes.

13 Q. Okay. Based off of this
14 document, Bergen Brunswick Drug Corporation
15 developed this suspicious order reporting
16 system in '96 to '98 with the DEA?

17 MR. FINKELSTEIN: Scope.

18 Foundation. Calls for speculation.

19 THE WITNESS: From the various
20 letters that you've given me, Bergen
21 Brunswick came with a system that they
22 wanted to show us, asked us for our
23 input. So they showed us the design
24 of what they were -- the design of the
25 system that they were proposing to put

1 nationwide.

2 So we provided input. We

3 tested it with them. So, yes.

4 QUESTIONS BY MR. MAHADY:

5 Q. Okay. So, yes, the DEA

6 developed the program -- the design of the

7 program with Bergen Brunswig, correct?

8 MR. FINKELSTEIN: Asked and

9 answered. Scope. Foundation.

10 You can answer.

11 THE WITNESS: We did not design

12 it. It said -- I mean, if we go back

13 to the September letter, it says it's

14 to introduce the DEA to the innovative

15 new system under development by Bergen

16 Brunswig.

17 So Bergen Brunswig, as of

18 September 30th, was the one that says,

19 "Hey, we have this new system." So

20 they came to us and said, "Hey, could

21 you review it, help us with it," which

22 is exactly what we do with

23 registrants. We do do that. We

24 listen. We present -- the registrant

25 is to design it; not us. So in

1 designing it, Bergen Brunswig came to
2 us. So this is between Bergen and us.

3 QUESTIONS BY MR. MAHADY:

4 Q. Between Bergen and the DEA?

5 A. DEA, right.

6 Q. Okay. And in designing it, the
7 DEA provided input on the design, correct?

8 A. Yes.

9 MR. FINKELSTEIN: Wait, scope.

10 THE WITNESS: Sorry.

11 QUESTIONS BY MR. MAHADY:

12 Q. And the DEA tested the program,
13 correct?

14 MR. FINKELSTEIN: Scope.

15 THE WITNESS: Yes.

16 QUESTIONS BY MR. MAHADY:

17 Q. And the DEA, based off of this
18 document, was very pleased with how the
19 suspicious order monitoring program was being
20 run, correct?

21 MR. FINKELSTEIN: Scope. Calls
22 for speculation.

23 THE WITNESS: That's what it
24 appears from the letter.

25

1 QUESTIONS BY MR. MAHADY:

2 Q. Okay. Next paragraph. "We are
3 confident that this new suspicious order
4 reporting system will benefit both BBDC and
5 DEA and are optimistic that we will be able
6 to begin implementation of the new suspicious
7 order -- or suspicious reporting system
8 nationwide. I believe that the new system
9 will not only save both BBDC and DEA valuable
10 time and resources, but will also provide DEA
11 with a more useful tool with which to detect
12 diversion."

13 Did I read that correctly?

14 A. Yes.

15 Q. Okay. "BBDC is excited about
16 this opportunity and would like to continue
17 moving forward with the implementation of our
18 new suspicious order reporting system."

19 Did I read that correctly?

20 A. Yes.

21 Q. So there's no dispute here that
22 this is -- this relates to the development of
23 a suspicious order reporting system, correct?

24 MR. FINKELSTEIN: Scope.

25 THE WITNESS: Well, I mean, it

1 references back to the September 30 --
2 September 30, 1996, where they explain
3 what it is, which we just talked
4 about, excessive purchase
5 after-the-fact reporting.

6 QUESTIONS BY MR. MAHADY:

7 Q. Mr. Prevoznik, they were
8 developing a suspicious order reporting
9 system, correct?

10 MR. FINKELSTEIN:

11 Argumentative. Asked and answered.

12 Scope. Calls for speculation.

13 You can answer.

14 MR. FARRELL: Objection, again,
15 on behalf of plaintiffs. We've never
16 even seen this system that they're
17 talking about.

18 THE WITNESS: Could you please
19 repeat it?

20 MR. MAHADY: Just note for the
21 record that plaintiffs have had this
22 document for approximately ten months.

23 MR. FARRELL: The ABDC system,
24 suspicious order monitoring system,
25 from 1996?

1 MR. MAHADY: You've had these
2 documents for ten months, Paul.

3 MR. FARRELL: Yeah. My
4 understanding is the last version of
5 the suspicious order monitoring system
6 produced by ABDC is when?

7 Excuse me. My point is that --

8 MR. NICHOLAS: He doesn't have
9 to answer your questions.

10 MR. MAHADY: Paul, I don't have
11 to answer your questions.

12 MR. NICHOLAS: You're running
13 the clock. Okay. Let him ask his
14 questions. You don't have to smirk
15 about it either. It's not that funny.

16 Go ahead.

17 THE WITNESS: I'm sorry, can
18 you please repeat it?

19 MR. MAHADY: Neither of us
20 remember it, so I'll take a shot.

21 QUESTIONS BY MR. MAHADY:

22 Q. The DEA and Bergen Brunswig
23 were developing a suspicious order monitoring
24 system that Bergen Brunswig intended to meet
25 the requirements of the regulations, correct?

1 MR. FINKELSTEIN: Scope.

2 Foundation. Calls for speculation.

3 That one mischaracterizes prior

4 testimony. Asked and answered.

5 You can answer again.

6 THE WITNESS: Can you -- can

7 you --

8 QUESTIONS BY MR. MAHADY:

9 Q. Bergen Brunswick and the DEA
10 were developing a suspicious order monitoring
11 system, correct?

12 MR. FINKELSTEIN:

13 Mischaracterizes prior testimony.

14 Scope.

15 MR. MAHADY: It was a question.

16 It wasn't even about his prior

17 testimony. I'm just asking a

18 question.

19 THE WITNESS: Bergen Brunswick
20 was designing a system, and they asked
21 us to review it and test it with them.

22 That's what we did.

23 QUESTIONS BY MR. MAHADY:

24 Q. And the system they were
25 designing was a suspicious order monitoring

1 system, correct?

2 MR. FINKELSTEIN: Asked and
3 answered. Calls for speculation.

4 You can answer again.

5 THE WITNESS: Based on the
6 regulations and the statute to
7 maintain effective controls, the
8 September 30th letter talks about
9 after-the-fact shipping. So it
10 doesn't -- it's not in accordance with
11 DEA policy as being -- suspicious
12 orders are prior to shipping.

13 QUESTIONS BY MR. MAHADY:

14 Q. Okay. And the DEA --

15 A. So the September 30th is
16 specifically talking about shipping. So it's
17 been shipped. That's what it -- that's what
18 the September 30th letter you gave me
19 indicates, that it's been shipped.

20 Q. Now, we've seen at least two
21 responses from DEA about the program.
22 They're approving a suspicious order
23 monitoring system, right?

24 MR. FINKELSTEIN:

25 Argumentative. Asked and answered.

1 You can answer.

2 THE WITNESS: They're approving
3 the system -- they're approving the
4 implementation of the system that
5 Bergen Brunswig designed. That's what
6 they're approving.

7 QUESTIONS BY MR. MAHADY:

8 Q. Okay. We can go back to
9 Prevoznik 22, please.

10 A. 22.

11 Q. Mr. Prevoznik, we've already
12 looked at this document, but now that we've
13 reviewed what the program consisted of, I
14 just want to ask a couple follow-up
15 questions.

16 First sentence of this document
17 from Patricia Good, chief liaison and policy
18 section, states, "This is to grant approval
19 of your request to implement on a nationwide
20 basis your newly developed system to identify
21 and report suspicious orders for controlled
22 substances and regulated chemicals as
23 required by federal regulation."

24 Correct?

25 A. Correct, that's what it says.

1 Q. And the subject of this
2 document that was drafted by the DEA, within
3 the possession, custody and control of the
4 DEA and produced in {sic} the DEA in this
5 litigation, is "approved suspicious order
6 monitoring system"; is that correct?

7 A. Yes, that's what it says.

8 Q. Okay. Mr. Prevoznik, before
9 the break I think we established that
10 Mr. Gitchel, who at one time served as the
11 chief of the liaison and policy section, was
12 inconsistent in the guidance he reported to
13 registrants relating to the suspicious order
14 regulations, correct?

15 MR. FINKELSTEIN: Objection.

16 Foundation.

17 THE WITNESS: That was --

18 MR. FINKELSTEIN: Wait. Scope.

19 You can answer in your personal
20 capacity.

21 THE WITNESS: Yeah, I answered
22 in my personal capacity. I said yes.

23 QUESTIONS BY MR. MAHADY:

24 Q. Okay. And I believe what we
25 were comparing there was Mr. Gitchel's

1 guidance in 1984 versus the guidance that he
2 was providing in relation to the more recent
3 development of the Bergen Brunswig suspicious
4 order monitoring system, correct?

5 MR. FINKELSTEIN: Foundation.
6 Scope.

7 THE WITNESS: Can you give it
8 to me one more time?

9 QUESTIONS BY MR. MAHADY:

10 Q. The inconsistency that
11 Mr. Gitchel was providing to the registrants,
12 one was in 1984 where, based off of your
13 testimony, Mr. Gitchel was advising
14 registrants that they should not ship orders
15 that they reported as suspicious, correct?

16 MR. FINKELSTEIN: Vague.
17 Foundation. Mischaracterizes the
18 document.

19 THE WITNESS: Yes.

20 QUESTIONS BY MR. MAHADY:

21 Q. Versus 1996 or '7 where
22 Mr. Gitchel, who was then the chief of the
23 liaison policy section of the DEA, is
24 referring to a monthly report of
25 after-the-fact purchases as a suspicious

1 order report and also advising on a
2 suspicious order monitoring system that would
3 entail after-the-fact reporting, right?

4 MR. FINKELSTEIN: Object to the
5 form.

6 THE WITNESS: Make sure I got
7 this right.

8 The design is by the
9 registrant. Then we get into the
10 operate -- the operation of it by the
11 registrant.

12 So the inconsistency -- which
13 I'm talking of me answering this
14 question -- is that the -- it just
15 seems a little convoluted, from me
16 reading this, that the excessive
17 purchase and the suspicious orders
18 were being referred to as the same
19 thing when indeed they are not.

20 Because the reg -- because the
21 statute and regulations of then DEA
22 policy, regulations haven't changed
23 since they came into effect. The
24 statute hasn't changed.

25 So we have been consistent

1 with -- DEA's consistency has been
2 that, where I think the
3 inconsistency -- this is me
4 speaking -- is that those two words
5 have been interchanged. Because it's
6 still referring to after-the-fact
7 shipments, and suspicious orders are
8 before shipment.

9 QUESTIONS BY MR. MAHADY:

10 Q. Okay. Mr. Prevoznik, the DEA
11 approved for implementation nationwide a
12 suspicious order monitoring system that
13 reported suspicious orders to the DEA on a
14 daily basis after the report -- after the
15 orders had already been shipped, correct?

16 A. Yes.

17 Q. Mr. Prevoznik, are you aware
18 that Bergen Brunswig merged with Amerisource
19 in or around 2001 to become AmerisourceBergen
20 Corporation?

21 MR. FINKELSTEIN: Objection.
22 Scope.

23 THE WITNESS: I know they
24 merged. I don't know what year.

25

1 QUESTIONS BY MR. MAHADY:

2 Q. That's fair.

3 And what was your role at the
4 DEA in the early 2000s?

5 A. 2001 I was -- I got promoted to
6 instructor at DEA officer training.

7 Q. Okay. And in your role as --
8 at the office of training, you were
9 personally familiar with AmerisourceBergen,
10 Bergen Brunswig's, system, correct?

11 A. What do you mean?

12 Q. Do you recall taking the
13 training classes to the Bergen Brunswig,
14 AmerisourceBergen distribution centers in
15 Richmond, Virginia?

16 A. Yes.

17 (Prevoznik Exhibit 27 marked
18 for identification.)

19 MR. MAHADY: Okay. I'm going
20 to mark this next document as
21 Prevoznik 27.

22 Unfortunately, I have short
23 arms, Mr. Prevoznik, so...

24 MR. FINKELSTEIN: The important
25 thing is, do you have extra copies?

1 MR. MAHADY: I do. And I'll
2 use my short arms to get you one.

3 MR. FINKELSTEIN: Thank you.

4 QUESTIONS BY MR. MAHADY:

5 Q. Okay. I'm going to read this
6 letter, which is dated January 14, 2004,
7 Bates number ABDC MDL 00315827. And it's
8 from a John R. McCarty, special agent in
9 charge, to Mr. Mays, manager of regulatory
10 affairs, AmerisourceBergen.

11 I want to read the first
12 paragraph of this letter.

13 "This letter is to confirm
14 previous arrangements made by the Drug
15 Enforcement Administration, DEA, office of
16 training class coordinator, Thomas Prevoznik,
17 for a tour of the Bergen Brunswick facility in
18 Richmond, Virginia, by our diversion
19 investigator trainees. I appreciate your
20 cooperation, and I'm certain that the visit
21 to your distribution plant will be a valuable
22 learning experience for our students."

23 Okay. So I believe you already
24 testified that you do recall some trainings
25 that were provided by AmerisourceBergen at

1 its distribution center in Virginia to the
2 diversion investigator trainees, correct?

3 A. Yes.

4 Q. Okay. And do you recall those
5 trainings involved discussions about the
6 applicable rules and regulation that govern
7 distributors?

8 A. Yes.

9 Q. Okay. And by bringing your
10 diversion investigator trainees to
11 AmerisourceBergen, you obviously thought that
12 there was value in AmerisourceBergen advising
13 them of what their understanding of the
14 regulations were, correct?

15 MR. FINKELSTEIN: Objection.

16 Scope.

17 You can answer.

18 THE WITNESS: I'm sorry, can
19 you repeat the -- repeat the question?

20 QUESTIONS BY MR. MAHADY:

21 Q. Well, by bringing your
22 diversion investigator trainees to
23 AmerisourceBergen and having
24 AmerisourceBergen present on the DEA's rules
25 and regulations, you certainly thought that

1 AmerisourceBergen was complying with those
2 rules and regulations, right?

3 MR. FINKELSTEIN: Objection.
4 Scope. Mischaracterizes the document.

5 THE WITNESS: I mean, the goal
6 wasn't for them to -- the goal was to
7 expose them to a real registrant. So
8 give them -- they had -- we go through
9 security, we go through records,
10 reports, all of those kinds of things
11 while we're at training.

12 We don't have huge cages. We
13 don't have a bunch of cameras. We
14 don't have any of the practical things
15 that the registrant has, especially
16 Bergen Brunswig. At this time at this
17 distribution center they had cages,
18 the locks, the alarms, that kind of
19 thing.

20 So that was -- that was to get
21 them out to expose them to that type
22 of a real practical application.

23 QUESTIONS BY MR. MAHADY:

24 Q. Understood.

25 A. Right?

1 So part of it was they also --

2 I believe Steve actually gave the
3 presentation. And he talked about the
4 interaction with DEA, because that's what we
5 were trying -- these were all new trainees,
6 so they had never been exposed to any of
7 this.

8 So we thought this was a great
9 opportunity for that --

10 Q. Okay.

11 A. -- collaboration.

12 Q. And that was valuable -- that
13 was, in fact, a valuable experience for your
14 diversion investigator trainees?

15 MR. FINKELSTEIN: Scope.

16 THE WITNESS: Yes.

17 QUESTIONS BY MR. MAHADY:

18 Q. Okay. And AmerisourceBergen
19 partnered with you to provide that training,
20 right?

21 A. Yes.

22 (Prevoznik Exhibit 28 marked
23 for identification.)

24 QUESTIONS BY MR. MAHADY:

25 Q. Okay. I'm going to mark

1 exhibit Prevoznik 28. Provide a copy to the
2 government.

3 You're free to look at the
4 presentation, but I'm only going to ask you
5 questions about the cover document.

6 A. Okay.

7 Q. Let me know when you're ready.
8 The document is Bates-labeled ABDC MDL
9 00315829.

10 Ready?

11 A. Yeah.

12 Q. This is an internal
13 AmerisourceBergen memorandum dated
14 October 25, 2004. Subject, ABC awarded DEA
15 certificate of appreciation.

16 I'm going to read the document.

17 "As many of you already know,
18 CSRA regularly provides training for
19 diversion investigator trainees from DEA's
20 Quantico, Virginia training academy. This
21 training takes place at AmerisourceBergen's
22 Richmond distribution center and includes a
23 tour of the facility.

24 "At the conclusion of the
25 training on Friday, October 22, 2004, DEA

1 presented AmerisourceBergen Corporation with
2 a certificate of appreciation in recognition
3 of ABC's contributions to drug enforcement
4 and to DEA's training program. Steve Mays
5 accepted the award on behalf of
6 AmerisourceBergen."

7 Do you recall DEA awarded
8 AmerisourceBergen a certificate of
9 appreciation in 2004?

10 MR. FINKELSTEIN: Scope.

11 THE WITNESS: Yes.

12 QUESTIONS BY MR. MAHADY:

13 Q. Okay. And they were deserving
14 of that recognition?

15 MR. FINKELSTEIN: Scope.

16 THE WITNESS: Yes.

17 QUESTIONS BY MR. MAHADY:

18 Q. You can put that document
19 aside, Mr. Prevoznik.

20 Now, fortunately for you, I do
21 want to revisit P22, which is the DEA
22 memorandum summarizing the distributor
23 initiative conference presentation with
24 AmerisourceBergen.

25 A. Thank you.

1 MR. FINKELSTEIN: This is
2 Prevoznik 22 or Plaintiff's 22?

3 MR. MAHADY: Plaintiff's 22.

4 MR. FINKELSTEIN: Plaintiff's
5 22. Give me a second.

6 THE WITNESS: It's way at the
7 bottom.

8 QUESTIONS BY MR. MAHADY:

9 Q. I know you already looked at
10 this this morning.

11 Are you okay for me to proceed
12 asking questions?

13 A. Yes.

14 Q. All right. Again, internal
15 memorandum of the DEA. This document
16 summarizes the DEA's understanding or summary
17 of the meeting, correct?

18 A. Correct.

19 Q. Okay. You do not attend these
20 meetings?

21 A. No.

22 Q. Okay. And just, again, so the
23 record's clear, it's from Michael Mapes.

24 You did not speak with Michael
25 Mapes in preparation for your testimony

1 today?

2 A. No.

3 Q. Okay. The last sentence of the
4 first paragraph, it says, "The purpose of the
5 meeting was to address the illegal domestic
6 Internet pharmacy problem and their source of
7 supply."

8 Did I read that correctly?

9 A. Yes.

10 Q. And that's your understanding
11 of the purpose of the meeting?

12 A. Yes.

13 Q. Okay. If we turn to the next
14 page, I want to start -- I want to read the
15 sentence -- the paragraph that starts, "In
16 consultation with Mr. Trant."

17 Do you know who Mr. Trant is?

18 A. He was an attorney with our
19 Chief Counsel.

20 Q. Okay. So he's DEA?

21 A. Yes.

22 Q. Okay. And E-Commerce
23 Operations, ODCO, that's DEA as well, right?

24 A. Yes, that was Mr. Mapes'
25 section.

1 Q. Got it.

2 And based off of the DEA's
3 summary of the meeting, it says, "In
4 consultation with Mr. Trant, it was agreed
5 that if E-Commerce Operations, ODCO, were to
6 identify a highly suspicious pharmacy to
7 which AmerisourceBergen was the wholesaler,
8 ODCO would notify AmerisourceBergen via
9 e-mail of the suspicious activity for
10 AmerisourceBergen to review and take the
11 actions the company deems appropriate."

12 Did I read that correctly?

13 A. Yes.

14 Q. Okay. So at this meeting, the
15 DEA represented to Mr. Steve Mays of
16 AmerisourceBergen that if the DEA identified
17 a highly suspicious pharmacy to which
18 AmerisourceBergen was the wholesaler, it
19 would notify AmerisourceBergen via e-mail of
20 that pharmacy, correct?

21 A. That's what it says.

22 Q. Okay. As the representative of
23 the DEA, do you know if the DEA identified
24 highly suspicious pharmacies to
25 AmerisourceBergen?

1 MR. FINKELSTEIN: I'm going to
2 object and instruct you not to answer.

3 We had a separate witness for
4 this topic. AmerisourceBergen had the
5 opportunity to ask questions then and
6 they didn't. This witness has not
7 been designated to answer questions
8 about this topic.

9 MR. MAHADY: This witness has
10 already testified in response to
11 questions from plaintiffs about the
12 substance of these meetings. These
13 questions are based directly on what
14 was represented by the DEA at the
15 meeting.

16 MR. FINKELSTEIN: So he can
17 definitely talk about the distributor
18 initiative briefing, including the one
19 to AmerisourceBergen. But if the
20 question is DEA's practice of
21 notifying registrants when a different
22 registrant suspended orders to a
23 particular suspicious customer, that's
24 a separate topic.

25 We had a whole different

1 witness, we had a deposition of that
2 witness, and this is not the witness.

3 MR. MAHADY: Let's keep moving.

4 QUESTIONS BY MR. MAHADY:

5 Q. This one-and-a-half-page
6 summary of the meeting prepared by DEA about
7 the DEA's meeting with AmerisourceBergen,
8 does it say in here, in this summary,
9 anywhere, that the DEA advised
10 AmerisourceBergen that it should not ship
11 orders that it reports as suspicious in
12 the -- I'm not talking about the
13 presentation, we'll get to that in a second,
14 but in the summary itself.

15 A. No.

16 Q. Okay. If you can turn to --
17 sticking with this document but turning to
18 the PowerPoint, I want to revisit the slide
19 that you looked at earlier with either
20 Mr. Farrell or Ms. Singer about suspicious
21 orders. It's on page 7, Bates ending in 155.

22 A. Okay.

23 Q. Okay. "Suspicious orders.
24 Reporting a suspicious order to DEA does not
25 relieve the distributor of the responsibility

1 to maintain effective controls against
2 diversion."

3 If I understood your testimony
4 earlier, you testified that this was the DEA
5 telling the registrants in 2005 that they
6 should not report orders that they deemed
7 suspicious; is that correct?

8 MR. FINKELSTEIN: Objection.
9 Mischaracterizes the testimony.

10 THE WITNESS: Did you just say
11 that the DEA -- I'm not sure I
12 understood what you just said. I
13 thought you said that they weren't
14 supposed to tell us.

15 QUESTIONS BY MR. MAHADY:

16 Q. You testified this morning --

17 A. Right.

18 Q. -- and correct me if I'm wrong,
19 that it was this slide through which the DEA
20 was telling the distributors that they should
21 not ship an order that they report to the DEA
22 as suspicious.

23 Was that your testimony this
24 morning?

25 A. The reporting of suspicious

1 order to the DEA does not relieve -- so after
2 the fact, yeah.

3 Q. Okay. If the DEA did not want
4 the distributors to ship orders that were
5 reported as suspicious, or stated
6 differently, after-the-fact reporting, why
7 didn't the DEA just say that?

8 A. I think it does say that.

9 Q. This --

10 A. Because the statute says you
11 have to maintain effective controls to guard
12 against diversion.

13 Q. Right.

14 But we've already --

15 MR. FINKELSTEIN: Let the
16 witness answer.

17 QUESTIONS BY MR. MAHADY:

18 Q. Go ahead.

19 A. So the statute's already saying
20 you have to have something in place to
21 maintain effective controls. So if you
22 identify a suspicious order, which is prior
23 to shipping, you have to alleviate that.
24 Otherwise, you're just shipping -- you're
25 just shipping suspicious -- the orders that

1 you have a reason or reason to believe that
2 it's going to be going to the illicit market.

3 So if you don't take the step
4 to alleviate the suspicions, then the
5 suspicions are still going down the line.
6 It's not -- it's not stopping.

7 Q. Mr. Prevoznik, I think we've
8 already established that the regulation does
9 not explicitly say do not ship orders that
10 you report as suspicious, right?

11 A. I agree with that, but the
12 statute says you have to have effective
13 means. So if -- effective means is -- if
14 you're -- this whole business is purchasing
15 and selling of controlled substances.

16 A DEA registration, that's what
17 gives you the authority to do it legally in
18 the United States. So once you become a DEA
19 registrant, there's statutes and there's
20 regulations that you have to follow.

21 Q. Understood.

22 A. And the public interest
23 requires that you maintain effective controls
24 of diversion.

25 So if a suspicious order is

1 prior to shipment, which is -- DEA's
2 interpreted that, then it just -- a
3 reasonable deduction is that you shouldn't be
4 sending these down the line if you don't
5 alleviate that suspicion.

6 Q. Mr. Prevoznik, we've already
7 established that the DEA approved a system
8 with after-the-fact reporting.

9 MR. FINKELSTEIN: Objection.

10 QUESTIONS BY MR. MAHADY:

11 Q. We also established that the
12 guidance from the DEA, including the guidance
13 provided by the chief of the section
14 responsible for interpreting the DEA, was at
15 times inconsistent on this very issue, right?

16 MR. FINKELSTEIN: Objection.

17 Argumentative. Also object as to the
18 form.

19 QUESTIONS BY MR. MAHADY:

20 Q. We've already established that.

21 MR. FINKELSTEIN: Objection.

22 Argumentative.

23 You don't have to accept
24 counsel's representations as to what
25 we've established.

1 MR. MAHADY: That's a speaking
2 objection. We can limit the
3 objections, please.

4 MR. FINKELSTEIN: He's arguing
5 with the witness about what we've
6 established.

7 SPECIAL MASTER COHEN: You can
8 answer the question.

9 THE WITNESS: I would say -- I
10 said from my personal view of reading
11 the thing that there was
12 inconsistency. I'm not speaking on
13 the DEA's behalf on that. So I don't
14 think that's consistent with what your
15 interpretation of what I said was.

16 QUESTIONS BY MR. MAHADY:

17 Q. Okay. And --

18 A. And I also said that the
19 request was can we implement the system that
20 Bergen designed. And we said yes, and we
21 worked with you to do that.

22 Q. Okay.

23 A. So again, it's the design, and
24 now we go to operation.

25 Q. Got it.

1 And the system --

2 MR. FINKELSTEIN: Let the
3 witness answer.

4 QUESTIONS BY MR. MAHADY:

5 Q. I'm sorry, Mr. Prevoznik. Were
6 you done or not?

7 A. So the operation now becomes
8 what was actually implemented.

9 Q. Okay.

10 A. Did Bergen follow it. So
11 that's why we do scheduled investigations.
12 That's why we come out and we review, and we
13 look at your -- are you following what you
14 say you're following. That's what we do.

15 Q. Okay. And the system that was
16 designed, that the DEA approved to implement,
17 using your words, had after-the-fact
18 reporting, correct?

19 MR. FINKELSTEIN: Asked and
20 answered.

21 THE WITNESS: Yes.

22 QUESTIONS BY MR. MAHADY:

23 Q. Okay. Mr. Prevoznik, I believe
24 on day one of your testimony you were asked
25 questions about specific DEA pharmaceutical

1 industry conferences, correct?

2 A. Yes.

3 Q. And I believe you came back
4 from a break and you identified some of the
5 industry conferences that have been held over
6 the years.

7 A. Yes, I forgot them.

8 Q. Perfectly understandable.

9 And one of the ones that you
10 identified was the Houston pharmaceutical
11 industry conference in September of 2007,
12 right?

13 A. Yes.

14 Q. Okay. And I'm going to mark
15 this as an exhibit.

16 (Prevoznik Exhibit 29 marked
17 for identification.)

18 QUESTIONS BY MR. MAHADY:

19 Q. You can feel free to read the
20 whole document. I'm going to ask you about
21 this section, suspicious orders, on page 2.

22 Okay?

23 A. Okay.

24 Q. This document does not have a
25 Bates number. I'll represent for the record

1 that I printed it from the DEA's website
2 yesterday.

3 A. Okay.

4 Q. Okay. On page 2, section
5 captioned "Suspicious Orders."

6 With me?

7 A. Yep.

8 Q. Okay. The document reads,
9 "Michael Mapes, chief DEA regulatory section,
10 and Chris Zimmerman, vice president,
11 corporate security and regulatory affairs,
12 AmerisourceBergen, updated the attendees on
13 when suspicious orders -- reports should be
14 submitted to authorities."

15 Did I read that correctly?

16 A. Yes.

17 Q. Okay. If you go to the end of
18 that section, it says, "Presentation slides
19 attached."

20 Have you reviewed any
21 presentation slides from the 2007 industry
22 conference relating to the presentation
23 provided by Mr. Zimmerman and Mr. Mapes?

24 A. No. We couldn't find them.

25 Q. Okay. And a company can't just

1 show up and present at the DEA's industry
2 conference; they have to be invited to
3 present by the DEA, right?

4 A. Yes.

5 Q. Okay. And based off of this
6 summary from the DEA's website, Mr. Zimmerman
7 and Mr. Mapes, who was then at the DEA, were
8 updating the attendees on when suspicious
9 order reports should be submitted to
10 authorities.

11 Did I read that correctly?

12 A. Yes.

13 (Prevoznik Exhibit 30 marked
14 for identification.)

15 QUESTIONS BY MR. MAHADY:

16 Q. Okay. Now, I'm going to mark
17 as Prevoznik 30 a copy of the September 11,
18 2007 presentation that Mr. Zimmerman and
19 Mr. Mapes gave at the conference.

20 And I'm not going to ask you
21 about the entire presentation. I'm only
22 going to ask you about a couple different
23 slides.

24 So let me know when you're
25 ready for questions.

1 A. I'm ready.

2 Q. All right. And before I do so,
3 do you remember --

4 MR. FINKELSTEIN: What's your
5 basis for saying Mr. Mapes gave this
6 presentation?

7 MR. MAHADY: The printout from
8 the DEA's website that Mr. Mapes and
9 Mr. Zimmerman gave a presentation on
10 suspicious order.

11 MR. FINKELSTEIN: But this just
12 says Zimmerman on it.

13 MR. MAHADY: That's fine. I
14 can restate.

15 I'll represent for the record
16 that the document only says
17 Mr. Zimmerman.

18 QUESTIONS BY MR. MAHADY:

19 Q. This morning, in response to
20 questions from Ms. Singer, I believe you
21 testified that the DEA has consistently
22 advised registrants that chain pharmacies
23 should be treated no differently than
24 independent retail pharmacies.

25 Was that your testimony?

1 A. Yes.

2 Q. Okay. And if you turn to
3 ABDCMDL0037190, I have a couple questions on
4 that point.

5 You with me?

6 A. Yep.

7 Q. All right. The slide is
8 captioned, "New Customer Due Diligence." The
9 first bullet, "Know your customer, due
10 diligence, investigations completed on all
11 new retail and wholesale accounts."

12 Did I read that correctly?

13 A. Yes.

14 Q. It then says, "Retail chain
15 pharmacies are exempted."

16 That -- did I read that
17 correctly?

18 A. Yes.

19 Q. Okay. And that piece of
20 information was presented by Mr. Zimmerman at
21 the DEA distributor initiative conference,
22 correct?

23 A. Yes.

24 Q. And that piece of guidance was
25 provided to all registrants in attendance,

1 correct?

2 MR. FINKELSTEIN: Object to the
3 characterization.

4 THE WITNESS: Yes, this is
5 Mr. Zimmerman's presentation. Yes.

6 QUESTIONS BY MR. MAHADY:

7 Q. Okay. Are you aware that the
8 DEA informed AmerisourceBergen that retail
9 chain pharmacies were exempted from the know
10 your customer requirements?

11 MR. FINKELSTEIN: Objection.
12 Foundation.

13 THE WITNESS: No.

14 QUESTIONS BY MR. MAHADY:

15 Q. Okay. But this was a
16 presentation that Chris Zimmerman gave at the
17 invitation of the DEA, correct?

18 A. Correct.

19 Q. Okay. Now, if you turn two
20 slides -- before we get to -- this is the
21 slide captioned "Order Monitoring Program."

22 A. Is that 192?

23 Q. Yep.

24 Before we talk about the slide
25 itself, Chris Zimmerman, he was the

1 individual from Bergen Brunswig who was
2 communicating with Mr. Gitchel and later
3 Ms. Good of the DEA, right?

4 A. Yes.

5 Q. Okay. And so he was very
6 familiar with the program that was approved
7 for implementation by the DEA, right?

8 MR. FINKELSTEIN: Objection.
9 Scope. Calls for speculation.

10 THE WITNESS: Yes.

11 QUESTIONS BY MR. MAHADY:

12 Q. Okay. Mr. Zimmerman says here,
13 "Historically" -- in the second bullet,
14 "Historically, controlled substances listed
15 chemical order monitoring has been based on a
16 ship and report process."

17 Did I read that correctly?

18 A. Yes.

19 Q. And "ship and report," that's
20 in bold, right?

21 A. Yes.

22 Q. So he's emphasizing the ship
23 and report, right?

24 MR. FINKELSTEIN: Objection.
25 Scope. Calls for speculation.

1 QUESTIONS BY MR. MAHADY:

2 Q. Correct?

3 A. Yes, it appears to be.

4 Q. Okay. And then it goes on to

5 say, "ABC's OMP process is now based on

6 identify, capture, investigate and report

7 suspicious orders, all prior to shipment."

8 Did I read that correctly?

9 A. Yes.

10 Q. And "prior to shipment" is

11 emphasized?

12 A. Yes, it's in bold.

13 Q. Okay. Did anyone at DEA stand

14 up at this conference and say,

15 "Mr. Zimmerman, what are you talking about?

16 Order monitoring has never been based on a

17 ship and report process"?

18 MR. FINKELSTEIN: Scope.

19 THE WITNESS: I don't know. I

20 wasn't there. I don't know.

21 I do know based on what's on

22 the line, it said Mr. Mapes stated

23 that the responsibility for making the

24 decision to ship rests with the

25 supplier.

1 QUESTIONS BY MR. MAHADY:

2 Q. But online --

3 A. Registrants who routinely
4 report suspicious orders, yet fill these
5 orders with reason to believe they are
6 destined for the illicit market, are failing
7 to maintain effective controls against
8 diversion.

9 Q. Okay.

10 A. That's what Mr. Mapes said --

11 Q. Right. And that's --

12 A. -- according to this report.

13 Q. And I appreciate that, and
14 that's based off of the 2007 guidance.

15 But it also says, "Michael
16 Mapes, chief, regulatory section, and Chris
17 Zimmerman, vice president, corporate security
18 of regulatory affairs, AmerisourceBergen,
19 updated the attendees on when suspicious
20 order reports should be submitted to
21 authorities."

22 This is the update, right?

23 MR. FINKELSTEIN: Objection.

24 Argumentative. Scope.

25 You can answer.

1 THE WITNESS: Well, no, I would
2 say this -- Mr. Zimmerman presented
3 what he understood as
4 AmerisourceBergen, and Mr. Mapes then
5 clarified what our position was when
6 he made that statement.

7 QUESTIONS BY MR. MAHADY:

8 Q. Okay.

9 A. But I'm just basically going
10 off the documents because I wasn't there.

11 Q. All right.

12 MR. FINKELSTEIN: Let's take
13 our next break in a couple of minutes.

14 MR. MAHADY: Yep.

15 QUESTIONS BY MR. MAHADY:

16 Q. Earlier today Ms. Singer showed
17 you Diversion Investigator Manuals, correct?

18 A. Yes.

19 Q. You don't have to take them
20 out.

21 A. Okay.

22 Q. I don't think so.

23 Diversion Investigator Manuals,
24 those are internal DEA documents, right?

25 A. Yes.

1 Q. Okay. And what's contained in
2 the Diversion Investigator Manuals is not
3 shared with the public, correct?

4 A. Correct.

5 Q. Okay. And so a registrant
6 can't just go online and look up the DEA's
7 Diversion Investigator Manuals from 1990,
8 correct?

9 A. Correct.

10 Q. Okay. And so when those
11 Diversion Investigator Manuals were in
12 effect, AmerisourceBergen did not have a copy
13 of that manual, right?

14 MR. FINKELSTEIN: Calls for
15 speculation. Scope.

16 THE WITNESS: Not to my
17 knowledge.

18 QUESTIONS BY MR. MAHADY:

19 Q. Okay. And the guidance that
20 was in those Diversion Investigator Manuals,
21 there was no tracking system at the DEA to
22 ensure that all diversion investigators were
23 getting guidance consistent with what was
24 contained in those manuals, correct?

25 MR. FINKELSTEIN: Vague.

1 THE WITNESS: I'm not sure I'm
2 following you on that one.

3 QUESTIONS BY MR. MAHADY:

4 Q. There's no way to know whether
5 or not the diversion investigators deviated
6 from what was in those manuals, correct?

7 A. Correct.

8 MR. FINKELSTEIN: Vague.
9 Scope.

10 THE WITNESS: Sorry. Sorry.
11 No.

12 MR. MAHADY: Let's take our
13 break.

14 MR. FINKELSTEIN: Okay. Thank
15 you.

16 VIDEOGRAPHER: We're going off
17 record. The time is 3:40.

18 (Off the record at 3:40 p.m.)

19 VIDEOGRAPHER: We're going back
20 on the record. Beginning of Media
21 File Number 8. The time is 3:51.

22 EXAMINATION

23 QUESTIONS BY MS. FUMERTON:

24 Q. Good afternoon, Mr. Prevoznik.
25 My name is Tara Fumerton. And I know we met

1 during the break, but just for the record, I
2 represent Walmart in this litigation, and I
3 just have a few questions for you that
4 hopefully we'll be able to get through
5 quickly. I'm going to jump around a little
6 bit, so I apologize if it doesn't quite flow.

7 Just as a cleanup and to orient
8 you, during the second day of your testimony
9 you confirmed that the DEA did not meet with
10 CVS, Rite Aid, Walmart, Walgreens or HBC
11 Giant Eagle as part of DEA's distributor
12 initiative concerning Internet pharmacies,
13 correct?

14 A. Correct.

15 Q. And my colleague then asked you
16 a follow-up question to that, and the answer
17 got a little bit muddled, so I just wanted to
18 clear it up.

19 He asked whether the DEA
20 conducted a distributor briefing with these
21 same retail chain pharmacies related to rogue
22 pain clinics.

23 And just so that the record is
24 clear, the DEA did not conduct any
25 distributor briefing with the retail chain

1 pharmacies related to rogue pain clinics,
2 correct?

3 MR. FINKELSTEIN: Vague.

4 THE WITNESS: Yes, but we did
5 meet with them in the fall of 2013,
6 the chain -- the chain pharmacies'
7 managements.

8 QUESTIONS BY MS. FUMERTON:

9 Q. And when you say "the chain
10 pharmacies' management," what do you mean?

11 A. We had been doing the pharmacy
12 diversion awareness conferences, and during
13 like the first four, I think it was the first
14 four of these meetings, during breaks we
15 would be kind of scattered and being pulled
16 aside by a lot of -- quite a few pharmacists
17 and pharmacy techs. Sometimes they would say
18 where they were from. A lot of times they
19 would say they were from a chain. And we
20 would have discussions about what was going
21 on in those chains.

22 So after about the fourth
23 conference, Mr. Rannazzisi said, all right,
24 I've had enough. Let's get the top 33 chain
25 pharmacies. I want their executive

1 management there at a meeting at NABP.

2 I was not at that meeting, but
3 it was held at NABP. And the topics that the
4 pharmacists and the pharmacy techs from those
5 chain stores had -- that were brought up were
6 discussed with the executive management.

7 Q. So to be clear, you're talking
8 about a side meeting that occurred at an
9 industrywide conference; is that correct?

10 A. It's not -- it wasn't an
11 industry -- it was specifically for like the
12 top 30, 30, 35 chain pharmacies, that we
13 invited them to come to NABP, the National
14 Board of Pharmacies.

15 Q. And that's 2013, correct?
16 Approximately?

17 A. I think it was the fall
18 of 2012, to be honest with you.

19 Q. Okay. But that was not a
20 distributor --

21 A. No.

22 Q. -- briefing --

23 A. Correct.

24 Q. -- that you had testified about
25 previously, correct?

1 A. Correct.

2 Q. So there was not a distributor
3 briefing with the chain pharmacies, correct?

4 A. Correct.

5 MR. FARRELL: I'm not going to
6 take your time. You used the chain
7 pharmacies with a different lingo.

8 When you're talking chain
9 pharmacies, are you talking about in
10 their role as a distributor?

11 MS. FUMERTON: Yes.

12 QUESTIONS BY MS. FUMERTON:

13 Q. Now, this morning Ms. Singer
14 asked you a series of questions about HDMA
15 industry compliance guidelines marked as
16 Plaintiff's Exhibit 39 and various HDMA
17 activities.

18 Do you recall that line of
19 questioning?

20 A. Yes.

21 Q. You were aware that Walmart was
22 not a member of HDMA, correct?

23 MR. FINKELSTEIN: Objection.

24 Scope.

25 THE WITNESS: I was not aware.

1 QUESTIONS BY MS. FUMERTON:

2 Q. Do you know one way or another
3 whether or not Walmart was a member of HDMA?

4 A. I don't. I personally don't
5 know.

6 Q. If I represent that Walmart was
7 not a member of HDMA, do you have any reason
8 to disagree with that representation?

9 MR. FINKELSTEIN: Scope. Calls
10 for speculation.

11 THE WITNESS: No.

12 QUESTIONS BY MS. FUMERTON:

13 Q. But you do know, because you
14 testified previously about this, that Walmart
15 only distributed controlled substances to
16 their own stores, correct?

17 MR. FINKELSTEIN: Scope. Calls
18 for speculation.

19 THE WITNESS: Yes. I don't --
20 I don't know if there was a Walmart
21 pharmacy that may have sold to
22 somebody else, but that would be down
23 the line.

24 Overall I know that it was --
25 Walmart's distribution centers sent it

1 to Walmart stores.

2 QUESTIONS BY MS. FUMERTON:

3 Q. And your other commentary after
4 you said "yes" was simply pure speculation on
5 your part, correct?

6 A. Correct.

7 Q. Walmart was not a wholesale
8 distributor of controlled substances,
9 correct?

10 MR. FINKELSTEIN: Scope.

11 THE WITNESS: What do you mean
12 by that?

13 QUESTIONS BY MS. FUMERTON:

14 Q. Well, various terms have been
15 used by plaintiffs when asking questions, and
16 what I'm distinguishing between are
17 distributors who distribute the wholesale to
18 many different pharmacies, independent and
19 the like, and a distributor like Walmart that
20 only self-distributes controlled substances.

21 Do you understand that
22 distinction?

23 A. Yes, correct.

24 Q. Okay. So under that
25 distinction, Walmart is not a wholesale

1 distributor of controlled substances,
2 correct?

3 MR. FINKELSTEIN: Scope.

4 THE WITNESS: Correct.

5 QUESTIONS BY MS. FUMERTON:

6 Q. And that's true for Rite Aid as
7 well, correct?

8 MR. FINKELSTEIN: Scope.

9 THE WITNESS: Yes.

10 QUESTIONS BY MS. FUMERTON:

11 Q. And Walgreens, CVS and HBC
12 Giant Eagle, correct?

13 MR. FINKELSTEIN: Scope.

14 THE WITNESS: Yes.

15 QUESTIONS BY MS. FUMERTON:

16 Q. And would you agree that
17 nonmembers -- well, let me strike that.

18 You would agree that there may
19 be reasons why nonmembers of HDMA do not need
20 to follow HDMA guidelines, correct?

21 MR. FINKELSTEIN: Scope.

22 Vague.

23 THE WITNESS: I don't even know
24 that the HDMA members have to follow
25 the guidelines either. I mean, the

1 registrants have to make their
2 decisions based on the registration.

3 HDMA is not a registrant.

4 QUESTIONS BY MS. FUMERTON:

5 Q. You would agree that nonmembers
6 of HDMA might have different business models
7 than HDMA members, correct?

8 A. Yes. Yes.

9 MR. FINKELSTEIN: Wait a
10 minute.

11 THE WITNESS: Oh, sorry.

12 MR. FINKELSTEIN: Scope. Calls
13 for speculation.

14 QUESTIONS BY MS. FUMERTON:

15 Q. And the DEA expects that each
16 registrant will review its own business model
17 and design a SOM system that fits its
18 designed method of distribution, correct?

19 A. Yes.

20 Q. Mr. Prevoznik, you're familiar
21 with immediate suspension orders, correct?

22 A. Yes.

23 Q. Are immediate suspension orders
24 also sometimes referred to as ISOs?

25 A. Yes.

1 Q. And an immediate suspension
2 order gives DEA the power, without notice, to
3 immediately freeze the prescribing ability of
4 a doctor who DEA believes is diverting
5 prescription opioids, correct?

6 A. Well, it could be used for
7 that. It could be used for other things,
8 too.

9 Q. But that's one of the things
10 that it could be used for, correct?

11 A. Correct.

12 Q. And an immediate suspension
13 order is an important tool to DEA because it
14 immediately stops the hemorrhaging caused by
15 a doctor who is diverting prescription
16 opioids, correct?

17 A. Again, yes, but it could be
18 more than that.

19 Q. So an immediate suspension
20 order gives DEA the ability to immediately
21 stop the diversion and then backtrack and
22 build a criminal case against the diverting
23 doctor, correct?

24 A. Well, sometimes they run
25 parallel.

1 Q. Sometimes --

2 A. So it's already -- both are
3 already ongoing.

4 Q. Sometimes it can run parallel.
5 But are you also aware that during the 2006
6 to 2015 time frame when Mr. Rannazzisi ran
7 DEA's Office of Diversion Control, DEA
8 sometimes delayed filing an immediate
9 suspension order to allow investigators to
10 gather evidence for a criminal case?

11 MR. FINKELSTEIN: Scope.

12 THE WITNESS: I don't have
13 specifics, but I know that that did
14 happen.

15 MS. FUMERTON: And just to
16 briefly address the scope objection,
17 Mr. Farrell started out with one of
18 his very first questions on day two to
19 Mr. Prevoznik: "The million dollar
20 question right out of the gate is why
21 didn't the DEA do more?" And then he
22 went on to ask a series of questions
23 relating to the DEA's actions and to
24 Mr. Patterson's -- and played
25 Mr. Patterson's testimony.

1 And the government didn't once
2 make an objection to scope as to any
3 of that testimony.

4 So I would ask that either I'm
5 permitted to ask these questions or
6 all of Mr. Farrell's testimony -- or
7 all of Mr. Farrell's questions along
8 those lines be stricken.

9 MR. FINKELSTEIN: Without
10 prejudice to your motion to strike,
11 are you asking for an instruction that
12 I not object to your questions?

13 MS. FUMERTON: No, I'm asking
14 for --

15 MR. FINKELSTEIN: Good. I'll
16 make my objections. Thank you,
17 Counsel.

18 MS. FUMERTON: Okay. Well, I
19 will also then continue.

20 And as I want to make for the
21 record, though, the fact that the
22 government is being inconsistent with
23 respect to its objections regarding
24 scope, depending on whether or not
25 plaintiff's counsel or defendant's

1 counsel is asking the question.

2 MR. FINKELSTEIN: We believe
3 we're being consistent.

4 You can ask your next question.

5 MR. FARRELL: And I prefer my
6 questions not be stricken.

7 MS. FUMERTON: And with that,
8 I've lost track of where we are. Give
9 me one second.

10 QUESTIONS BY MS. FUMERTON:

11 Q. Okay. So you -- just to
12 reorient us, you agree that sometimes the DEA
13 would delay issuing an ISO with respect to a
14 doctor that it was investigating for
15 potentially diverting controlled substances,
16 correct?

17 MR. FINKELSTEIN: Scope.

18 And I'm going to add that
19 you're instructed not to testify based
20 on nonpublic, law-enforcement-
21 sensitive information.

22 THE WITNESS: Based on that,
23 that advice, I can't answer that one.

24 QUESTIONS BY MS. FUMERTON:

25 Q. Okay. Well, I'm going to show

1 you what was previously marked as Prevoznik
2 Exhibit 17.

3 And I apologize, I only have
4 two copies because I thought we would have
5 other copies here.

6 And, Mr. Prevoznik, do you
7 recall --

8 MS. SINGER: I'm sorry, what is
9 it?

10 MS. FUMERTON: It's Exhibit 17.

11 QUESTIONS BY MS. FUMERTON:

12 Q. Do you recall reviewing this
13 exhibit in your prior testimony?

14 A. Yes.

15 Q. I think your instruction by
16 counsel was to not answer the question unless
17 it was public information; is that correct?

18 A. Law enforcement sensitive.

19 Q. Well, Exhibit 17 is testimony
20 before Congress, correct, dated March 20,
21 2018?

22 A. Yes.

23 Q. And you previously testified
24 about Mr. Patterson's other comments at this
25 hearing, correct?

1 A. Correct.

2 MR. FINKELSTEIN: Lest there be
3 any doubt, you're permitted to testify
4 about Prevoznik 17.

5 QUESTIONS BY MS. FUMERTON:

6 Q. So I want to turn your
7 attention to page 54.

8 A. Okay.

9 Q. Okay. And specifically turn to
10 questioning, just to orient everybody, by
11 Congresswoman Susan Brooks to Mr. Patterson.
12 And if you look about three -- one-third way
13 down the page, you'll see a question by
14 Mr. -- I'm sorry, by Mrs. Brooks, and she
15 asks: "Are there instances in which the DEA
16 pursues an immediate suspension order, the
17 ISO, in parallel with related potential
18 criminal investigation?"

19 Do you see that?

20 A. Yes.

21 Q. And Mr. Patterson replies:

22 "So, ma'am, since October, so the
23 administration's -- the administrator's
24 position signs the ISOs when they're issued.
25 What I've traditionally seen is because of

1 the process of where a criminal case is being
2 investigated, there's been a delay in the ISO
3 process as they're gathering evidence. One
4 of the concerns I have, and it goes back to
5 again what Mr. Griffith said, is that cuts
6 against the very argument that we have an
7 imminent problem that we are trying to deal
8 with."

9 Do you see that?

10 A. Yes.

11 Q. And so Mr. Patterson was
12 testifying here that the DEA, in fact, was
13 delaying in issuing ISOs to allow criminal
14 investigations to occur, correct?

15 MR. FINKELSTEIN: Objection.

16 Mischaracterizes the document.

17 You can answer.

18 THE WITNESS: Yes.

19 MS. SINGER: Can I just
20 interject and ask that you get copies
21 at the next break in case there's any
22 redirect that needs to be done here?
23 It's a little unfair to question the
24 witness when there isn't a copy of the
25 exhibit.

1 MS. FUMERTON: Well, you can
2 use one of the government's exhibits
3 or we can get a copy if you need that
4 as well. But it was used previously,
5 so you should have a copy from the
6 prior time's exhibit.

7 MS. MAINIGI: It's your
8 document, Linda.

9 QUESTIONS BY MS. FUMERTON:

10 Q. And then if you go down on that
11 same page, about to the bottom third, you'll
12 see another question from Mrs. Brooks, and
13 she asks: "And are you saying that the US
14 Attorneys were asking -- as a former
15 US Attorney, are you saying that US Attorneys
16 were asking or telling DEA not to issue
17 ISOs?"

18 And Mr. Patterson replies: "In
19 trying to gather evidence in their criminal
20 case."

21 Mrs. Brooks responds: "I
22 understand, but that can take months, if not
23 years, sometimes in criminal cases. Do you
24 believe that's what happened prior to you
25 coming in October of 2017, that delays

1 happened?"

2 And Mr. Patterson replies: "I
3 think that's been an ongoing theme of what
4 some of these delays are caused by."

5 Do you see that?

6 A. Yes.

7 Q. Do you have any reason to
8 disagree with Mr. Patterson's testimony?

9 MR. FINKELSTEIN: Scope.

10 THE WITNESS: No.

11 QUESTIONS BY MS. FUMERTON:

12 Q. And so that meant that for
13 months, if not years, while these
14 investigations were occurring, the DEA
15 permitted doctors it believed were diverting
16 opioids to continue to divert opioids,
17 correct?

18 MR. FINKELSTEIN: Foundation.

19 Argumentative.

20 THE WITNESS: I'm sorry, can
21 you repeat it?

22 QUESTIONS BY MS. FUMERTON:

23 Q. Sure.

24 And so that means that for
25 months, if not years, the DEA permitted

1 doctors it believed were diverting opioids to
2 continue to divert opioids, correct?

3 MR. FINKELSTEIN: Same
4 objections.

5 THE WITNESS: It's possible,
6 yeah.

7 MS. FUMERTON: I am going to
8 pass the witness at this time.

9 Thank you very much for your
10 time.

11 Can we go off the record while
12 we switch?

13 VIDEOGRAPHER: We're going off
14 the record. The time is 4:07.

15 (Off the record at 4:07 p.m.)

16 VIDEOGRAPHER: We're going back
17 on record. Beginning of Media File
18 Number 9. Time is 4:08.

19 EXAMINATION

20 QUESTIONS BY MR. O'CONNOR:

21 Q. Mr. Prevoznik, I'm Andrew
22 O'Connor. I represent one of the
23 manufacturers in the case. We met last time
24 we were here.

25 A. Good to see you again.

1 Q. Good to see you.

2 I'll try to be brief here.

3 Is it fair for me to say that
4 DEA does not advise registrants on whether
5 they have an adequate and effective
6 suspicious order monitoring program?

7 A. We don't advise?

8 Q. Correct.

9 A. No, I don't think that's fair
10 to say that. I think when we -- when we sit
11 down and talk to them and they present what
12 they're having, we're in listening mode. We
13 offer suggestions, so that would be advising.

14 Q. Okay. Does DEA approve any
15 particular suspicious order monitoring
16 program?

17 A. No.

18 Q. And why is that?

19 A. Because it's ultimately -- it's
20 incumbent upon the registrant to design and
21 operate the system, so it's a business
22 decision made by the registrant.

23 Q. And I believe you testified
24 earlier to the fact that one of the reasons
25 is because the registrant is the one that has

1 relevant information.

2 Is that a fair characterization
3 of what you said earlier?

4 A. They're in a better position.
5 They deal with the customer on a more daily
6 basis.

7 Q. And would you say they're in a
8 better position than DEA?

9 A. To assess their customer? Yes.

10 Q. And to assess the adequacy and
11 effectiveness of their suspicious order
12 monitoring program?

13 A. I'm sorry, you're losing me on
14 that one.

15 Q. Would you say that a registrant
16 is in a better position than DEA to assess
17 the adequacy and effectiveness of its
18 suspicious order monitoring program?

19 MR. FINKELSTEIN: Objection.

20 Vague.

21 THE WITNESS: No, I wouldn't
22 agree with that.

23 QUESTIONS BY MR. O'CONNOR:

24 Q. Okay. So DEA is in a better
25 position than the registrant to assess the

1 program?

2 MR. FINKELSTEIN: Vague.

3 Mischaracterizes prior testimony.

4 THE WITNESS: I think -- I
5 think, again, it's the design and it's
6 the operating. So what is the
7 operating -- what is the registrant
8 doing to make the -- when they
9 implement it, what are they -- what
10 are -- are they following the
11 guidelines that they said that they
12 were going to design, or are they
13 starting the shift to change when a
14 customer comes in and asks for -- is
15 on-boarding. Are they looking at all
16 the parameters that the customer --
17 whether it's the questionnaire. Are
18 they validating all those types of
19 things.

20 It has to do with are they
21 increasing thresholds when they're
22 asked for a threshold increase. Are
23 they just arbitrarily increasing it to
24 some higher number or is there a
25 scientific basis that makes that

1 determination.

2 So that's what we look at when
3 we go back and look at the system.

4 QUESTIONS BY MR. O'CONNOR:

5 Q. I just want to get back to my
6 question, because I had understood your
7 testimony earlier today to be that DEA would
8 not weigh in on the adequacy of a suspicious
9 order monitoring program because it was the
10 registrant and not DEA who had the right
11 information to make that assessment.

12 MR. FINKELSTEIN: Asked and
13 answered. Mischaracterizes prior
14 testimony.

15 QUESTIONS BY MR. O'CONNOR:

16 Q. Do you agree with my
17 characterization of what you said earlier
18 today?

19 A. No, I don't agree with your
20 characterization.

21 Q. Okay. So do you think the DEA
22 then is in a better position to make
23 assessments about the suspicious order
24 monitoring programs than the registrants are?

25 MR. FINKELSTEIN: Vague. Asked

1 and answered.

2 THE WITNESS: The suspicious
3 order monitoring system is incumbent
4 upon the registrant to design it and
5 operate it. They are in the position
6 that knows their customers. We don't
7 know their customers.

8 QUESTIONS BY MR. O'CONNOR:

9 Q. Okay. Only the registrant --

10 A. So therefore --

11 MR. FINKELSTEIN: Let him
12 finish.

13 THE WITNESS: So, therefore,
14 the registrant is in a better position
15 to assess their customers.

16 How they assess it is something
17 that they do and that we do.

18 QUESTIONS BY MR. O'CONNOR:

19 Q. Okay. Earlier today I believe
20 you testified that manufacturers should make
21 sure that distributors' suspicious order
22 monitoring programs are adequate and
23 effective.

24 Did I get that right?

25 A. Yeah, they should know what

1 their customer -- if the next -- if the next
2 line down is to the distributors, they should
3 know what kind of program they have.

4 Q. And I believe you indicated
5 it's DEA's position that manufacturers are
6 supposed to make that assessment of the
7 distributor's suspicious order monitoring
8 program before they begin a business
9 relationship with the distributor; is that
10 fair?

11 A. Yes. Know your customer.

12 Q. And just to be clear,
13 manufacturers are supposed to assess whether
14 the distributor's program is adequate and
15 effective?

16 A. They should know what it is,
17 but, again, as I -- manufacturers also
18 distribute not just to distributors. They
19 also go to practitioners, sometimes
20 pharmacies, directly. So they also have to
21 have the ability to have a suspicious order
22 monitoring system for those registrants as
23 well in place.

24 Q. I understand.

25 I just want to be very clear

1 about what the DEA contends a manufacturer
2 has to do, because earlier it sounded like
3 you were saying they need to assess whether a
4 distributor's suspicious order monitoring
5 program was, in fact, effective.

6 Is that correct?

7 A. Well, they should know if their
8 customer's system is guarding -- is it
9 guarding against the diversion into the
10 illicit market.

11 Q. And is the DEA's position that
12 they should make that assessment even in
13 situations where the DEA has refused to make
14 that assessment?

15 MR. FINKELSTEIN:

16 Argumentative. Foundation.

17 THE WITNESS: You lost me on
18 that one.

19 QUESTIONS BY MR. O'CONNOR:

20 Q. Well, DEA doesn't tell a
21 registrant whether its program works or not,
22 does it?

23 A. Well --

24 MR. FINKELSTEIN:

25 Mischaracterizes prior testimony.

1 THE WITNESS: When --

2 MR. O'CONNOR: Just a question.

3 THE WITNESS: When we sit with
4 the registrant, the registrant
5 explains what their ordering sys --
6 their suspicious order system is to
7 us.

8 So then when we come back, we
9 look. Are, in fact, they -- are they
10 doing what they said they're doing,
11 and is the system able to identify
12 suspicious orders. That's what we do.

13 And our parameters of doing
14 that are the public interest. So are
15 there -- do they have in place the
16 means to identify them and also
17 safeguard and have effective measures
18 to not allow for diversion.

19 QUESTIONS BY MR. O'CONNOR:

20 Q. Is there any statute or
21 regulation that you're aware of that says
22 manufacturers are supposed to assess whether
23 a distributor's suspicious order monitoring
24 program is adequate?

25 A. Not specifically that language.

1 Q. Okay.

2 A. It would fall under the statute
3 of effective means.

4 Q. And that provision that talks
5 about effective controls doesn't mention
6 anything about assessing another registrant's
7 suspicious order monitoring program, correct?

8 A. Correct.

9 Q. And DEA never issued any
10 guidance to manufacturers informing them that
11 they were supposed to assess another
12 registrant's program, correct?

13 A. Not to my knowledge.

14 Q. DEA never sent a letter to that
15 effect to manufacturers?

16 A. Probably happened in the
17 manufacturing -- when we met with the
18 manufacturer. Like the distributor
19 initiative with a manufacturer, we went over
20 that.

21 Q. Can you say, sitting here today
22 under oath, that that happened?

23 A. I don't know, but I --

24 Q. Okay. Earlier today I believe
25 you testified that manufacturers should

1 review -- or registrants generally should
2 review information regarding physician
3 prescribing information.

4 Is that a fair assessment of
5 what you said?

6 A. Yes, if they have it.

7 Q. Okay. Did DEA have physician
8 prescribing information?

9 MR. FINKELSTEIN: I'm going to
10 instruct you not to answer about the
11 availability of data sources to the
12 extent that they're nonpublic.

13 THE WITNESS: Could you repeat
14 the question?

15 QUESTIONS BY MR. O'CONNOR:

16 Q. Sure.

17 Did DEA have physician
18 prescribing information?

19 MR. FINKELSTEIN: And my
20 instruction, no nonpublic data or
21 techniques.

22 THE WITNESS: Right. No, we
23 didn't -- we have to get it through a
24 different means.

25 QUESTIONS BY MR. O'CONNOR:

1 Q. Okay. Let me ask you this:

2 Are you familiar with IMS or IQVIA data?

3 A. Yes.

4 Q. Did DEA have access to IMS or
5 IQVIA data that described the number of
6 prescriptions written by particular
7 physicians?

8 MR. FINKELSTEIN: Scope. No
9 law-enforcement-sensitive information.
10 Okay?

11 THE WITNESS: Yes.

12 We do use IQVIA data, but
13 that's for quotas. Quota section uses
14 that. It doesn't go down to that
15 granular -- that's my understanding,
16 it does not go down to that granular
17 level that you're describing.

18 We have asked. We have been
19 trying to get that data, but we have
20 been unsuccessful at this point.

21 QUESTIONS BY MR. O'CONNOR:

22 Q. And as someone who oversees the
23 targeting and analysis unit, if there was
24 information available publicly that you felt
25 was useful to the DEA identifying diversion,

1 you would seek it out, correct?

2 MR. FINKELSTEIN: Incomplete
3 hypothetical.

4 THE WITNESS: Yes.

5 QUESTIONS BY MR. O'CONNOR:

6 Q. Okay. But you do not have
7 prescriber-level IMS or IQVIA data, true?

8 MR. FINKELSTEIN: Same
9 instruction.

10 THE WITNESS: As I previously
11 said, we do have some, but it's used
12 at the quota level, not to the
13 granular level that you're talking
14 about. We do not have it.

15 QUESTIONS BY MR. O'CONNOR:

16 Q. And there is no statute or
17 regulation that you're aware of that
18 indicates that manufacturers were required to
19 analyze prescriber-level data in connection
20 with their DEA compliance activities,
21 correct?

22 MR. FINKELSTEIN: Asked and
23 answered.

24 THE WITNESS: Correct. But if
25 they have it, then they should look at

1 it.

2 QUESTIONS BY MR. O'CONNOR:

3 Q. Even though it's not in the
4 statute or the regulation?

5 A. It's knowing your customer.
6 It's putting effective means -- guarding
7 against diversion. So if the information
8 helps you understand your customer better and
9 stops diversion, then you should be looking
10 at it.

11 Q. Did DEA ever indicate in any
12 kind of written guidance document that
13 manufacturers should be analyzing prescriber
14 data in order to fulfill their DEA
15 obligations?

16 A. Not to my knowledge.

17 Q. DEA never sent any letters to
18 the industry to that effect?

19 A. I'm not aware of it.

20 Q. And DEA never posted anything
21 on its website informing manufacturers of its
22 view on this issue?

23 A. Not to my knowledge.

24 MR. O'CONNOR: Thank you for
25 your time.

1 Go off the record.

2 VIDEOGRAPHER: Going off the
3 record. The time is 4:19.

4 (Off the record at 4:19 p.m.)

5 VIDEOGRAPHER: Going back on
6 the record. Beginning of Media
7 File 10. The time is 4:20.

8 EXAMINATION

9 QUESTIONS BY MR. EPPICH:

10 Q. Good afternoon, Mr. Prevoznik.
11 You may recall my name is Chris Eppich, and I
12 represent the McKesson distributors in this
13 litigation. I just have a couple of
14 questions for you this afternoon.

15 Are you aware of the federal
16 sentencing guidelines?

17 MR. FINKELSTEIN: Scope.

18 THE WITNESS: Yes.

19 QUESTIONS BY MR. EPPICH:

20 Q. Are you aware that the federal
21 sentencing guidelines are used by courts in
22 sentencing after a verdict in a criminal
23 case?

24 MR. FINKELSTEIN: Scope.

25 THE WITNESS: Yes.

1 QUESTIONS BY MR. EPPICH:

2 Q. The DEA doesn't use the federal
3 sentencing guidelines to evaluate
4 registrants' suspicious order monitoring
5 programs, correct?

6 MR. FINKELSTEIN: Scope.
7 Vague.

8 THE WITNESS: Yes. Correct.

9 QUESTIONS BY MR. EPPICH:

10 Q. Correct that they do not?

11 A. Do not.

12 Q. Thank you, sir.

13 Now, when you were training
14 diversion investigators, did you ever
15 instruct diversion investigators to rely on
16 the federal sentencing guidelines to evaluate
17 registrants' suspicious order monitoring
18 programs?

19 MR. FINKELSTEIN: Scope.

20 THE WITNESS: No.

21 MR. EPPICH: Thank you. Let's
22 go off the record.

23 VIDEOGRAPHER: Going off
24 record. The time is 4:21.

25 (Off the record at 4:21 p.m.)

1 VIDEOGRAPHER: We're going back
2 on record. Beginning of Media
3 File 11. The time is 4:23.

4 EXAMINATION

5 QUESTIONS BY MS. MAINIGI:

6 Q. Mr. Prevoznik, you recall we
7 met a few weeks ago on the first day or two
8 of your deposition.

9 I'm going to ask you some more
10 questions. I'm here representing Cardinal
11 Health.

12 Mr. Prevoznik, you did not
13 speak to Mr. Mapes prior to coming here
14 today, did you?

15 MR. FINKELSTEIN: Asked and
16 answered several times.

17 THE WITNESS: No.

18 QUESTIONS BY MS. MAINIGI:

19 Q. Okay. And you had not spoken
20 to him prior to day one and day two?

21 A. Correct.

22 Q. And you did not speak to
23 Mr. Wright prior to coming today?

24 MR. FINKELSTEIN: Asked and
25 answered.

1 THE WITNESS: Correct.

2 QUESTIONS BY MS. MAINIGI:

3 Q. And is it true that you've only
4 still reviewed the questions from
5 Mr. Wright's deposition, not the answers?

6 A. Yes.

7 Q. You've never gone back to
8 review the answers to Mr. Wright's
9 deposition, only the questions?

10 A. Correct.

11 Q. And that was at the instruction
12 of your counsel?

13 MR. FINKELSTEIN: Objection.

14 I'm going to instruct you not
15 to answer that.

16 MS. MAINIGI: I think he
17 answered that before.

18 I'll withdraw the question.

19 MR. FINKELSTEIN: I don't think
20 he did, but I appreciate you
21 withdrawing the question.

22 QUESTIONS BY MS. MAINIGI:

23 Q. Mr. Prevoznik, you arrived at
24 the DEA in 1991; is that right?

25 A. Yes.

1 Q. And you were a diversion
2 investigator until 2001?

3 A. Well, I still think I am.

4 Q. That's right.

5 A. Still have the same job series.

6 Q. Your primary duty was as a
7 diversion investigator until 2001?

8 A. Yes.

9 Q. And in that situation, you were
10 out in the field offices?

11 A. Yes.

12 Q. Okay. And you joined the
13 Office of Diversion Control at headquarters
14 in May 2012?

15 A. I believe it was April.

16 Q. Okay. Now, the last several
17 days you've been asked a number of questions
18 about suspicious orders, true?

19 A. True.

20 Q. And suspicious, that term has a
21 particular meaning in the context of
22 controlled substances, correct?

23 A. Correct.

24 Q. And the CFR defines suspicious
25 order as including orders of unusual size,

1 orders of unusual frequency and orders that
2 deviate substantially from a normal ordering
3 pattern, correct?

4 A. Correct.

5 Q. Excuse me.

6 Now, not every order of unusual
7 size is indicative of diversion, correct?

8 MR. FINKELSTEIN: Asked and
9 answered.

10 THE WITNESS: Correct.

11 QUESTIONS BY MS. MAINIGI:

12 Q. There could be legitimate
13 reasons for a pharmacy to place an order of
14 unusual size, correct?

15 MR. FINKELSTEIN: Asked and
16 answered.

17 THE WITNESS: Correct.

18 QUESTIONS BY MS. MAINIGI:

19 Q. Can you think of any examples
20 that come to mind for that, Mr. Prevoznik?

21 MR. FINKELSTEIN: Calls for
22 speculation.

23 THE WITNESS: For which one?

24 QUESTIONS BY MS. MAINIGI:

25 Q. Why a pharmacy may place a

1 larger than usual order.

2 MR. FINKELSTEIN: Scope. Calls
3 for speculation.

4 You can answer in your
5 individual capacity.

6 THE WITNESS: It could be a new
7 hospital opened, a new clinic opened.
8 A new hospice center could have
9 opened. Any one of those.

10 QUESTIONS BY MS. MAINIGI:

11 Q. And, Mr. Prevoznik, not every
12 order of unusual frequency is indicative of
13 diversion, correct?

14 MR. FINKELSTEIN: Asked and
15 answered.

16 THE WITNESS: Correct.

17 QUESTIONS BY MS. MAINIGI:

18 Q. There could be legitimate
19 reasons for an order of unusual frequency,
20 true?

21 MR. FINKELSTEIN: Same
22 objection.

23 THE WITNESS: True.

24 QUESTIONS BY MS. MAINIGI:

25 Q. Can you think of some examples

1 as to why a pharmacy may place an order that
2 is of unusual frequency?

3 MR. FINKELSTEIN: Scope. Calls
4 for speculation.

5 You can answer in your
6 individual capacity.

7 THE WITNESS: Again, it could
8 be a new customer base, prescriber, a
9 new doctor's office opened.

10 That probably would be for a
11 period of time, and then it would not
12 keep going and going. It would level
13 out at some point.

14 QUESTIONS BY MS. MAINIGI:

15 Q. But it could certainly explain
16 a deviation that resulted in an unusual
17 frequency for a month or two, correct?

18 MR. FINKELSTEIN: Vague.

19 THE WITNESS: Yes.

20 QUESTIONS BY MS. MAINIGI:

21 Q. Now, Mr. Prevoznik, not every
22 order that deviates substantially from a
23 normal ordering pattern is indicative of
24 diversion, correct?

25 MR. FINKELSTEIN: Asked and

1 answered.

2 THE WITNESS: Correct.

3 QUESTIONS BY MS. MAINIGI:

4 Q. And could there be legitimate
5 reasons for an ordering pattern that is
6 abnormal in some manner?

7 A. Yeah, there could be.

8 Q. And what are some of those
9 reasons?

10 MR. FINKELSTEIN: Scope. Calls
11 for speculation.

12 You can answer in your
13 individual capacity.

14 THE WITNESS: I'm not really
15 sure I have an example off the top of
16 my head on that one right now.

17 QUESTIONS BY MS. MAINIGI:

18 Q. Well, how does one define a
19 normal ordering pattern or something that
20 diverges from a normal ordering pattern?

21 A. Well, the example I would give
22 you is you have a pharmacist, they have their
23 order, and they will put two down. But they
24 don't see that one of their employees, who is
25 either working or not working, has added to

1 the order. So they could be at their house,
2 whatever, added a bottle, two bottles, but
3 it's later.

4 So at the end of the day, the
5 pharmacist -- they know the pattern of the
6 pharmacist is not to review, that they just
7 hit "submit," but they know that they're
8 going to be on the job the next day. So they
9 come in the next day, they already know
10 there's two extra bottles or an extra bottle
11 coming in. So that they've been doing this
12 for months and month and months, that they've
13 been stealing from, diverting out of the
14 pharmacy, because they know the habits of the
15 pharmacist.

16 It could be at a hospital. It
17 could be at a -- just anywhere. If they know
18 the habits, they're going to figure it out.

19 Q. So the placing of an order of
20 unusual size, pattern or frequency, standing
21 alone, does not indicate that a customer is
22 diverting controlled substances, correct?

23 A. Well, I mean, it's disjunctive,
24 so it could be one of them; it could be two
25 of them; it could three of them; it could be

1 a combination.

2 And so in the example I
3 would -- I would say is -- I think I've used
4 it before was the veterinarian that is
5 ordering Vicodin with the acetaminophen that
6 is toxic to cats and dogs. So that in
7 itself, an order of that, would be why are
8 they doing that.

9 Q. But standing alone, without
10 follow-up due diligence, it is not
11 necessarily always possible to determine
12 whether an order that is an unusual size,
13 unusual pattern or frequency is, by itself,
14 for that reason, indicative of diversion,
15 correct?

16 MR. FINKELSTEIN: Asked and
17 answered. Incomplete hypothetical.

18 THE WITNESS: Correct.

19 QUESTIONS BY MS. MAINIGI:

20 Q. And so some sort of follow-up
21 due diligence needs to be done by the
22 distributor or registrant, correct?

23 MR. FINKELSTEIN: Incomplete
24 hypothetical. Asked and answered.

25 THE WITNESS: Right.

1 QUESTIONS BY MS. MAINIGI:

2 Q. And with respect to -- we've
3 talked a bit about due diligence in the last
4 couple of days of your deposition.

5 Do you recall that?

6 A. Yes.

7 Q. Okay. And with respect to --
8 you've been asked questions by both
9 Mr. Farrell and Ms. Singer about
10 documentation related to due diligence.

11 Do you recall that?

12 A. Yes.

13 Q. And I believe that you
14 indicated that there was not any sort of
15 requirement by the DEA of the maintenance of
16 due diligence files, correct?

17 MR. FINKELSTEIN:

18 Mischaracterizes prior testimony.

19 THE WITNESS: Yes.

20 QUESTIONS BY MS. MAINIGI:

21 Q. Now certainly the DEA's view
22 appears to be that due diligence is a good
23 practice or a best practice, fair?

24 MR. FINKELSTEIN: Foundation.

25 Mischaracterizes prior testimony.

1 THE WITNESS: Yes, it would be
2 good practice.

3 QUESTIONS BY MS. MAINIGI:

4 Q. And but the DEA has not issued
5 any sort of guidelines indicating how due
6 diligence should be conducted, true?

7 A. I mean, I would say that the
8 letters in 2006 and 2007 have certain
9 questions to be asked, so that's a guide of
10 what should be asked or what should be looked
11 for.

12 Q. Those are Mr. Rannazzisi's
13 letters?

14 A. Yes.

15 Q. And Mr. Rannazzisi's letters
16 touched on a few different areas, correct?

17 A. Correct.

18 Q. Let me try to focus on
19 guidelines that might be specific to the idea
20 of due diligence.

21 Are there -- are you aware of
22 DEA ever issuing any guidelines specific to
23 due diligence that describe how due diligence
24 should be conducted?

25 MR. FINKELSTEIN: Asked and

1 answered.

2 THE WITNESS: No, not -- it's
3 the statute and the regulation.

4 QUESTIONS BY MS. MAINIGI:

5 Q. And the statute and regulation
6 do not specifically speak to due diligence,
7 correct?

8 MR. FINKELSTEIN: Asked and
9 answered.

10 THE WITNESS: No. I mean, they
11 do, because they're saying you have to
12 have effective means to guard against
13 diversion. So that's the guide.

14 QUESTIONS BY MS. MAINIGI:

15 Q. Let me come back to -- it's
16 effective controls, correct?

17 A. Effective.

18 Q. Let me come back to that.
19 Let's focus just on the phrase "due
20 diligence."

21 Are you aware of the phrase
22 "due diligence" being in either the statute
23 or the regulation?

24 MR. FINKELSTEIN: Asked and
25 answered.

1 THE WITNESS: It's not.

2 QUESTIONS BY MS. MAINIGI:

3 Q. Now, you've referred, I think,
4 just now and in the last several days to the
5 term "effective controls," correct?

6 A. Correct.

7 Q. And that term is in the statute
8 or the regulation, correct?

9 MR. FINKELSTEIN: Asked and
10 answered.

11 THE WITNESS: Correct.

12 QUESTIONS BY MS. MAINIGI:

13 Q. Okay. Has the DEA ever
14 explained in guidance what effective controls
15 means?

16 MR. FINKELSTEIN: Vague. Asked
17 and answered.

18 THE WITNESS: Effective
19 controls. Well, they have to follow
20 the rest of the statute to meet
21 effective controls to guard against
22 diversion.

23 QUESTIONS BY MS. MAINIGI:

24 Q. So has the DEA ever issued any
25 guidance, Mr. Prevoznik, that serves as a

1 checklist, for example, of everything that
2 would go into effective controls?

3 MR. FINKELSTEIN: Vague. Asked
4 and answered.

5 THE WITNESS: Not to my
6 knowledge.

7 QUESTIONS BY MS. MAINIGI:

8 Q. Coming back to the concept of
9 due diligence, the DEA has not issued any
10 guidance specifying how long a registrant
11 must hold on to due diligence, correct?

12 A. Correct.

13 Q. Does the DEA have any sort of
14 guidelines as to how long the DEA is required
15 to hold on to certain types of documents?

16 MR. FINKELSTEIN: Scope.

17 You can answer, if you know.

18 THE WITNESS: Yes, they do.

19 QUESTIONS BY MS. MAINIGI:

20 Q. Can you describe some for me?

21 A. I don't know.

22 MR. FINKELSTEIN: Scope.

23 THE WITNESS: I don't know
24 them, but I know they're out there.

25

1 QUESTIONS BY MS. MAINIGI:

2 Q. They might have some sort of
3 requirement to hold on to documents or data
4 for seven years or something of the sort?

5 MR. FINKELSTEIN: Scope.

6 Foundation.

7 You can answer in your personal
8 capacity.

9 THE WITNESS: I know that there
10 are certain years that certain
11 documents can be -- that are supposed
12 to be either archived or -- and then
13 once it gets archived, I have no idea.

14 QUESTIONS BY MS. MAINIGI:

15 Q. Are there certain documents
16 that you hold on to in your job at DEA that
17 you hold on to for a certain number of years
18 because you know you're required to?

19 MR. FINKELSTEIN: Scope.

20 THE WITNESS: Yes.

21 QUESTIONS BY MS. MAINIGI:

22 Q. And what kind of documents are
23 those?

24 A. Oh --

25 MR. FINKELSTEIN: Scope.

1 MS. MAINIGI: I'm sorry.

2 THE WITNESS: I was waiting for
3 him.

4 MR. FINKELSTEIN: Scope.

5 You can answer in your personal
6 capacity.

7 THE WITNESS: I know that we
8 hold on to ARCOS, ARCOS data, drug
9 theft loss.

10 QUESTIONS BY MS. MAINIGI:

11 Q. And do you know approximately
12 how long you're required to hold on to ARCOS
13 data?

14 MR. FINKELSTEIN: Scope.

15 THE WITNESS: I don't know.

16 QUESTIONS BY MS. MAINIGI:

17 Q. The DEA has certainly never
18 issued any sort of guidance indicating that
19 registrants must hold on to due diligence
20 files for 15 years, correct?

21 A. Yes. The only guidance I know
22 is it's two years, two years for
23 recordkeeping for the registrant.

24 Q. Okay.

25 A. For us.

1 Q. But there's no requirement that
2 a due diligence file even be maintained,
3 correct?

4 A. Correct.

5 Q. So the two-year rule does not
6 apply to any due diligence files, per se,
7 correct?

8 A. Correct. I was just pointing
9 out that within the regs, there is records
10 for a two-year period.

11 Q. Due diligence is certainly an
12 important part of this process, right?

13 MR. FINKELSTEIN: Vague.

14 THE WITNESS: Yes.

15 QUESTIONS BY MS. MAINIGI:

16 Q. Why do you think the DEA has
17 never issued any specific guidance on due
18 diligence?

19 MR. FINKELSTEIN: Vague.

20 Instruct you not to answer to
21 the extent that the answer calls for
22 predecisional deliberative
23 communications within the Department
24 of Justice.

25 THE WITNESS: I don't know.

1 QUESTIONS BY MS. MAINIGI:

2 Q. Now, is there any sort of
3 requirement -- I'm going to come back to
4 suspicious orders.

5 Is there any kind of
6 requirement to hold on to suspicious orders
7 themselves that are reported?

8 MR. FINKELSTEIN: Vague.

9 THE WITNESS: I'm not sure I'm
10 following on that.

11 QUESTIONS BY MS. MAINIGI:

12 Q. Well, so, for example, if -- I
13 think when you were talking to one of the
14 other questioners, there was some reference
15 to perhaps at some point in time suspicious
16 orders being faxed in to the DEA.

17 Do you remember that
18 discussion?

19 A. Yes.

20 Q. Is there any sort of
21 requirement, either by the DEA or by the
22 registrant, to hold on to an actual
23 suspicious order being reported to the DEA?

24 MR. FINKELSTEIN: Scope.

25 Vague. Calls for speculation.

1 THE WITNESS: No.

2 QUESTIONS BY MS. MAINIGI:

3 Q. Has the DEA issued any sort of
4 guidance indicating how long a suspicious
5 order that's been reported must be
6 maintained?

7 A. No.

8 Q. Now, I think with one of the
9 prior questioners there was reference to --
10 well, let me back up.

11 You prepared back to 1996 for
12 this deposition, approximately, correct?

13 A. Well, I mean, I had -- I --
14 from the letters that you saw, I had some
15 letters from 1980s that I saw.

16 Q. So you prepared for various
17 earlier periods of time?

18 A. I looked for what I could find.

19 Q. Okay. And did you speak to any
20 folks in the field offices to help yourself
21 prepare for this deposition?

22 MR. FINKELSTEIN: Asked and
23 answered.

24 THE WITNESS: Yes.

25

1 QUESTIONS BY MS. MAINIGI:

2 Q. And who were the folks you
3 spoke to from the field office?

4 MR. FINKELSTEIN: Asked and
5 answered.

6 THE WITNESS: Scott Collier,
7 Ruth Carter, Susan Langston, Lisa
8 Sullivan, David White, Scott Garriott.
9 I'm trying to think.

10 QUESTIONS BY MS. MAINIGI:

11 Q. And those were all folks that
12 were in the field offices in years prior?

13 A. Yeah, they were in the field.
14 They've been -- they're in the field now.

15 Q. Okay. So you're aware through
16 your own experience in the field as well as
17 the conversations you had that the
18 requirement of the regulation and the statute
19 is that suspicious orders generally are
20 reported to the local or regional DEA
21 offices, correct?

22 A. Correct.

23 Q. And then it's up to the local
24 or regional DEA offices to ultimately make a
25 decision about whether to investigate a

1 suspicious order, correct?

2 A. That's part of the process.

3 The other part is if it's not in their area,
4 then they would send it to that respective
5 office. So that would be the other part.

6 Q. But once it gets to the right
7 regional office, it is incumbent upon that
8 regional office to make a decision about what
9 to do with a suspicious order, correct?

10 A. Correct.

11 Q. And is it fair to say not every
12 suspicious order that is reported to a
13 regional office actually results in some sort
14 of investigation?

15 MR. FINKELSTEIN: Asked and
16 answered.

17 THE WITNESS: Yes.

18 QUESTIONS BY MS. MAINIGI:

19 Q. Do you have any sense of how
20 many, percentagewise, ballpark, of actual
21 reported suspicious orders result in
22 investigations by the DEA?

23 MR. FINKELSTEIN: Scope. Asked
24 and answered. Calls for speculation.

25 THE WITNESS: No, I don't.

1 QUESTIONS BY MS. MAINIGI:

2 Q. Do you think more than half do?

3 MR. FINKELSTEIN: Same
4 objections.

5 You can answer in your personal
6 capacity.

7 THE WITNESS: No, I don't. I
8 don't know. I couldn't put a number
9 on it.

10 QUESTIONS BY MS. MAINIGI:

11 Q. You don't have any sort of
12 educated guess on that even?

13 MR. FINKELSTEIN: Same
14 objection.

15 You can answer in your personal
16 capacity.

17 THE WITNESS: The reports that
18 you got, it would be -- when we would
19 go out, we would be like, was one
20 filed or wasn't one filed.

21 So if one was filed, then we
22 would know -- we would typically go
23 out and ask: Why did you file this?

24 Because sometimes -- I mean, I
25 don't know -- what is the time frame

1 we're talking about? That would help
2 me a little bit.

3 QUESTIONS BY MS. MAINIGI:

4 Q. I'm sorry. Let's say 1996
5 through 2006 for the first time period.

6 A. So if they came in, then we
7 would follow up with the registrant and ask:
8 Why did you file this? Ask for a reason as
9 to why you filed this. Because sometimes it
10 was just a sheet of paper that said,
11 diazepam, one bottle of 500. Well, that
12 doesn't really give us much of a --
13 information to act on, so we would have to
14 follow up on that.

15 Q. And I think you spoke to
16 earlier the fact that sometimes suspicious
17 orders would be called in to the regional
18 office, correct?

19 A. Yes.

20 Q. And I assume that -- if we kind
21 of use 1996 as a baseline, that in the late
22 '90s, early aughts, there were often
23 suspicious orders called in to the regional
24 offices, true?

25 MR. FINKELSTEIN: Scope. Calls

1 for speculation.

2 THE WITNESS: I wouldn't say
3 often. I mean, it was more the
4 excessive purchase reports is what we
5 got.

6 QUESTIONS BY MS. MAINIGI:

7 Q. Well, and I asked you to just
8 focus on whatever universe of suspicious
9 orders you got in that time period. Let's
10 say late '90s, early aughts.

11 Of the suspicious orders that
12 were being reported in that time period, is
13 it fair to say that a good number were called
14 in to the regional offices?

15 MR. FINKELSTEIN: Scope.
16 Vague. Calls for speculation.

17 THE WITNESS: I personally
18 don't know because I worked in the
19 Philadelphia office, so I don't know
20 how registrants were reporting during
21 that period in '96.

22 QUESTIONS BY MS. MAINIGI:

23 Q. But you were in the
24 Philadelphia regional office, correct?

25 A. Correct.

1 Q. And were you generally aware of
2 registrants calling in to report suspicious
3 orders from time to time?

4 MR. FINKELSTEIN: Scope.

5 THE WITNESS: At that point, it
6 was more chemicals. They were calling
7 in chemicals.

8 QUESTIONS BY MS. MAINIGI:

9 Q. Because that --

10 A. That would be it. It was the
11 methamphet -- we had the methamphetamine
12 epidemic at that point.

13 Q. Because there was an obligation
14 to report not just suspicious orders of
15 controlled substances but suspicious orders
16 of meth as well, true?

17 A. Listed chemicals to -- that
18 make meth.

19 Q. But --

20 A. We would have loved to have the
21 means for meth, but...

22 MR. FINKELSTEIN: Tom, answer
23 the questions.

24 QUESTIONS BY MS. MAINIGI:

25 Q. The suspicious orders of -- the

1 suspicious orders that were reported for
2 controlled substances from time to time did
3 get phoned in, correct?

4 A. There were some that were
5 phoned in, yes.

6 Q. And there were some that were
7 faxed in, correct?

8 A. Correct.

9 Q. And what are the other means
10 that suspicious orders came in to the field
11 offices?

12 A. Mailed in. Pretty much it.
13 They were phone, fax or mail.

14 Q. Okay. And if a suspicious
15 order was phoned in, how did the DEA then
16 maintain a record of that suspicious order?

17 MR. FINKELSTEIN: '96 to 2006?

18 MS. MAINIGI: Sure. Go with
19 that.

20 THE WITNESS: Document.

21 QUESTIONS BY MS. MAINIGI:

22 Q. Documented?

23 A. Document.

24 Q. And then are those documents
25 still in existence?

1 MR. FINKELSTEIN: Scope.

2 You can answer, if you know.

3 THE WITNESS: Don't know.

4 QUESTIONS BY MS. MAINIGI:

5 Q. You don't know how long the DEA
6 was required to hold on to suspicious orders
7 reported?

8 MR. FINKELSTEIN: Scope.

9 THE WITNESS: I don't know.

10 QUESTIONS BY MS. MAINIGI:

11 Q. Okay. And would the suspicious
12 orders that were phoned or faxed in or mailed
13 in, for that matter, to the regional offices,
14 would they ever even find their way to
15 headquarters for any reason?

16 A. It was on --

17 MR. FINKELSTEIN: Scope. Calls
18 for speculation.

19 THE WITNESS: If it was on a
20 report it would, because the reports
21 get -- go to headquarters.

22 QUESTIONS BY MS. MAINIGI:

23 Q. If it was on what type of
24 report?

25 A. One of our official reports.

1 Q. An internal report?

2 A. An internal report, yes.

3 Q. And what are some of the type
4 of internal reports?

5 You don't need to describe them
6 for me, but just what are some of the types
7 of internal reports that would get sent from
8 the field offices to headquarters --

9 MR. FINKELSTEIN: Scope.

10 QUESTIONS BY MS. MAINIGI:

11 Q. -- that would contain
12 suspicious orders?

13 MR. FINKELSTEIN: Scope.

14 THE WITNESS: It could be
15 scheduled investigation reports. It
16 could be part of the preregistration.
17 It could just be the suspicious order
18 itself.

19 QUESTIONS BY MS. MAINIGI:

20 Q. And what are some of the
21 reasons that the suspicious orders would be
22 sent up to headquarters?

23 A. We have a system that all
24 reports have to go to this one section to
25 update a system that we have.

1 Q. That's the ARCOS system or some
2 other system?

3 A. No, some other system.

4 Q. What's the name of the system?

5 MR. FINKELSTEIN: Scope.

6 THE WITNESS: I mean, it's --

7 MR. FINKELSTEIN: Wait. Hang
8 on. If this was law enforcement
9 sensitive, don't testify.

10 QUESTIONS BY MS. MAINIGI:

11 Q. Is this related to law
12 enforcement?

13 A. Yes.

14 Q. Okay. We can -- I can withdraw
15 that question.

16 Now, let me take you -- let me
17 switch gears for a moment here.

18 I think either -- I think the
19 second day you testified, you were asked if
20 the DEA agreed that if the distributor
21 determined that an order is suspicious and
22 should be blocked, the distributor should
23 terminate all sales to that customer until
24 they can rule out diversion is occurring.

25 Do you recall that question?

1 A. Yeah, I recall the question.

2 Q. Vaguely?

3 A. Vaguely.

4 Q. Okay. Do you remember
5 answering along the lines of yes to that
6 question?

7 A. I might have. I don't
8 remember.

9 Q. Well, is that the case?
10 If the distributor determines
11 an order is suspicious and should be blocked,
12 the distributor needs to terminate all sales
13 to a customer?

14 MR. FINKELSTEIN: Incomplete
15 hypothetical.

16 QUESTIONS BY MS. MAINIGI:

17 Q. Until they can rule out that
18 diversion is occurring?

19 A. Yeah, it should hold it until
20 they can rule out the suspicion.

21 Q. Now, has DEA ever issued any
22 sort of guidance or pronouncement essentially
23 saying that you must -- as a distributor in
24 that circumstance, you must terminate all
25 future controlled substance sales to a

1 customer if you report an order to the DEA?

2 MR. FINKELSTEIN: Asked and
3 answered. Mischaracterizes the
4 testimony.

5 THE WITNESS: Well, it depends
6 what they're -- what are they sending
7 as the order. What is the order that
8 they're saying is suspicious, correct?

9 QUESTIONS BY MS. MAINIGI:

10 Q. Well, the distributor reports a
11 suspicious order for customer X.

12 A. Of what?

13 Q. Of controlled substances.

14 A. So they're reporting the entire
15 order as being suspicious?

16 Q. Correct.

17 That's what they're obligated
18 to do, correct? Right?

19 A. Correct.

20 Q. Okay. So they report a
21 suspicious order to the DEA for customer X.

22 Customer X may have other
23 orders that are pending down the line.
24 Should the distributor cut off all orders to
25 customer X?

1 MR. FINKELSTEIN: Asked and
2 answered. Incomplete hypothetical.

3 THE WITNESS: Well, first of
4 all, I think you started your
5 statement with the DEA reports it.
6 It's not DEA that reports the
7 suspicious order. It's the registrant
8 that --

9 QUESTIONS BY MS. MAINIGI:

10 Q. I'm sorry if I misspoke.

11 A. That's fine. I just want to
12 make sure we're clear on that.

13 Q. Absolutely.

14 A. So it's the registrant that
15 has -- the system that they have has deemed a
16 suspicious order, for a reason or reasons,
17 that they believe that this will -- that has
18 the potential to be diverted.

19 Q. Correct.

20 A. So that registrant has made the
21 decision -- has -- from their system they've
22 deemed it a suspicious order. So they should
23 not ship until -- if they choose to, if they
24 want to alleviate that suspicion. If they
25 choose not to, then they shouldn't ship.

1 But if they choose to, then it
2 becomes they need to look into it further to
3 alleviate that suspicion.

4 MR. FINKELSTEIN: Let's --

5 QUESTIONS BY MS. MAINIGI:

6 Q. So they shouldn't ship the
7 order, right?

8 MR. FINKELSTEIN: Just a
9 second. Let's take our final break
10 when you're done with this line of
11 questioning.

12 QUESTIONS BY MS. MAINIGI:

13 Q. So they shouldn't ship the
14 order, right?

15 MR. FINKELSTEIN: Incomplete
16 hypothetical.

17 THE WITNESS: When they deem --
18 when they've determined that it's
19 suspicious --

20 QUESTIONS BY MS. MAINIGI:

21 Q. Correct.

22 A. -- a suspicious order?

23 Correct.

24 Q. They shouldn't ship it?

25 A. Correct, they should not ship

1 it.

2 Q. Okay. But they could choose to
3 ship it if they wanted to. That's a business
4 judgment, right?

5 MR. FINKELSTEIN:

6 Mischaracterizes prior testimony.

7 THE WITNESS: They could ship
8 it if they -- yeah, it's a business
9 decision.

10 QUESTIONS BY MS. MAINIGI:

11 Q. So let's say they choose to not
12 ship it and hold the order. Are they then
13 required to not ship any orders to that same
14 customer?

15 MR. FINKELSTEIN: Incomplete
16 hypothetical. Asked and answered.

17 THE WITNESS: Have they
18 alleviated the suspicion? Did they do
19 anything to alleviate the suspicion?

20 If they haven't alleviated the
21 suspicion, then it's still a
22 suspicious order.

23 QUESTIONS BY MS. MAINIGI:

24 Q. Okay. I'm not talking about
25 that order; I'm talking about any additional

1 orders that may not appear suspicious.

2 So let's say they take a while
3 to investigate that particular suspicious
4 order. They don't send it out. But in the
5 meantime they have in the queue other orders
6 from that pharmacy that do not look
7 suspicious to them.

8 MR. FINKELSTEIN: Incomplete --

9 QUESTIONS BY MS. MAINIGI:

10 Q. Are they okay to ship those
11 orders?

12 MR. FINKELSTEIN: Incomplete
13 hypothetical.

14 THE WITNESS: Well, I think if
15 they have one in the queue that's
16 already saying it's suspicious, then I
17 would -- I would think that they would
18 be at least questioning it like, well,
19 what are they doing?

20 QUESTIONS BY MS. MAINIGI:

21 Q. Are they required to hold the
22 other orders that they don't deem to be
23 suspicious, or is it okay to exercise their
24 business judgment to send those orders on?

25 MR. FINKELSTEIN: Asked and

1 answered. Incomplete hypothetical.

2 And I'd appreciate the break.

3 THE WITNESS: Could you please

4 repeat it?

5 QUESTIONS BY MS. MAINIGI:

6 Q. Are they required to hold the
7 other orders that they don't view to be
8 suspicious, or is it okay for the distributor
9 in that instance to exercise their business
10 judgment and send those nonsuspicious orders
11 out?

12 MR. FINKELSTEIN: Asked and
13 answered. Incomplete hypothetical.

14 THE WITNESS: Yes.

15 QUESTIONS BY MS. MAINIGI:

16 Q. Yes what?

17 A. They can.

18 Q. Okay. They can ship those
19 other orders out?

20 A. Yes.

21 MS. MAINIGI: Okay. Let's go
22 ahead and take your break.

23 VIDEOGRAPHER: We're going off
24 record. The time is 4:53.

25 (Off the record at 4:53 p.m.)

1 VIDEOGRAPHER: We're going back
2 on record, beginning of Media File
3 Number 12. The time is 5:03.

4 QUESTIONS BY MS. MAINIGI:

5 Q. So, Mr. Prevoznik, just
6 following up on our last line of questioning,
7 is it fair to say that DEA has no internal
8 policy defining the circumstances under which
9 a distributor is required to terminate the
10 distribution of controlled substances to a
11 pharmacy?

12 MR. FINKELSTEIN: Objection.
13 Mischaracterizes his prior testimony.

14 THE WITNESS: Could you please
15 repeat that?

16 QUESTIONS BY MS. MAINIGI:

17 Q. Sure.
18 Is it fair to say that DEA has
19 no internal policy defining the circumstances
20 under which a distributor is required to
21 terminate the distribution of controlled
22 substances to a pharmacy?

23 A. Yes.

24 Q. Now, do you recall being asked
25 last time a number of questions about the

1 NWDA suspicious order monitoring system? And
2 we may have even looked at it today.

3 Do you remember that?

4 A. Yes.

5 Q. And I believe it was
6 Exhibit P7. If you don't have it handy, I am
7 sure we can get you a new copy.

8 MR. FINKELSTEIN: May the
9 record reflect that James is now
10 screwing with my exhibits, but I
11 appreciate it.

12 MS. MAINIGI: I think that's
13 obvious. It doesn't even need to be
14 reflected on the record.

15 QUESTIONS BY MS. MAINIGI:

16 Q. You got one, Mr. Prevoznik?

17 A. Yes.

18 Q. Okay. Perfect.

19 And I think it had been
20 previously marked P7 for the record.

21 Now, you testified you were --
22 you were familiar with this document. You
23 had looked at it in preparation for your
24 deposition?

25 A. Yes.

1 Q. Okay. And the NWDA, just for
2 the record, is the National Wholesale
3 Druggists' Association?

4 A. Yes.

5 Q. And that was the trade
6 organization for distributors at this point
7 in time, which is about 1993?

8 A. Yes.

9 Q. Now, can you tell us your
10 understanding of the purpose of this document
11 that describes the NWDA suspicious order
12 monitoring system?

13 MR. FINKELSTEIN: Calls for
14 speculation.

15 THE WITNESS: I think it was --
16 the association was assisting their
17 members to come up with a suspicious
18 order monitoring system that they
19 could use.

20 QUESTIONS BY MS. MAINIGI:

21 Q. And it appears that the NWDA
22 was working at that point in time with both
23 DOJ and the DEA in establishing controls
24 aimed at reducing diversion, fair?

25 MR. FINKELSTEIN: Scope. Calls

1 for speculation.

2 THE WITNESS: I'm not sure

3 where I see DOJ.

4 I see DEA listed. I don't see

5 DOJ.

6 QUESTIONS BY MS. MAINIGI:

7 Q. So if we take a look at page 1

8 of the NWDA document, Mr. Prevoznik --

9 A. Yes.

10 Q. -- second paragraph under

11 background, could you read that out loud?

12 A. "The National Wholesale

13 Druggists' Association voluntarily began

14 working with the Department of Justice, Drug

15 Enforcement Administration, in establishing

16 controls clearly aimed at reducing or

17 eliminating illegal product distribution."

18 Q. And why would the DEA have

19 worked with this trade organization to help

20 develop these controls?

21 MR. FINKELSTEIN: Foundation.

22 Calls for speculation.

23 THE WITNESS: To protect the

24 public.

25

1 QUESTIONS BY MS. MAINIGI:

2 Q. And the DEA at that point in
3 time thought it was a good thing to help a
4 trade organization develop guidelines because
5 it would help everybody, correct?

6 MR. FINKELSTEIN: Foundation.
7 Calls for speculation.

8 THE WITNESS: I -- yeah, I
9 mean -- yeah.

10 QUESTIONS BY MS. MAINIGI:

11 Q. Most of all, it would help the
12 public, as you said?

13 A. Yes.

14 Q. Now, the system -- I think you
15 went over this earlier. The system that they
16 came up with had two components to it, right?
17 It had the monthly after-the-fact reporting?

18 A. Are you on a specific page?

19 Q. It had the monthly
20 calculations, page 2.

21 Do you see it?

22 MR. FINKELSTEIN: Page 2 where?

23 MS. MAINIGI: Page 2 under
24 monthly calculations.

25 MR. FINKELSTEIN: Okay.

1 THE WITNESS: Okay.

2 QUESTIONS BY MS. MAINIGI:

3 Q. And then it had -- so was that
4 the monthly after-the-fact reporting?

5 A. Yes.

6 Q. Okay. And so essentially --
7 and then I think it's further described at
8 page 4.

9 Do you see that?

10 A. Where specifically on page 4?
11 The report --

12 Q. I think the top, the top part
13 of page 4. It kind of rolls into page 3 and
14 then the top part of page 4.

15 A. Okay.

16 Q. And then this also -- I think
17 Mr. Farrell asked you, and Ms. Singer may
18 have as well. On page 7, there's a part 2 to
19 the reporting. In addition to the
20 after-the-fact monthly reporting, there's a
21 reference to the single suspicious orders.

22 Do you see that?

23 A. Yes.

24 Q. Now, the DEA did not require
25 the single suspicious orders to be reported

1 in a specific way; is that right?

2 MR. FINKELSTEIN: Vague as to
3 time.

4 THE WITNESS: That's correct.

5 QUESTIONS BY MS. MAINIGI:

6 Q. And the DEA worked with NWDA to
7 come up with a reporting system for the
8 monthly after-the-fact reports, correct?

9 MR. FINKELSTEIN: Foundation.
10 Scope.

11 THE WITNESS: From my review of
12 the document, yes.

13 QUESTIONS BY MS. MAINIGI:

14 Q. And those monthly
15 after-the-fact reports were sometimes called,
16 but not always, excessive purchase reports,
17 true?

18 A. Yes, correct.

19 Q. So in working with the NWDA,
20 the DEA essentially supported the concept of
21 two tiers of reporting, true?

22 A. The excessive purchase after
23 the fact and identifying the suspicious order
24 prior to shipping? Yes.

25 Q. And is it fair to say that a

1 distributor that was sending in the excessive
2 purchase reports after the fact and was
3 calling or faxing in suspicious orders was in
4 compliance with these guidelines that DEA
5 worked on with the NWDEA {sic}?

6 MR. FINKELSTEIN: Vague.

7 Incomplete hypothetical. Scope.

8 THE WITNESS: So again, this
9 goes back to the design and the
10 operating. So this is the design.

11 So what -- what did the
12 registrant do to operate? I don't
13 know. It's --

14 QUESTIONS BY MS. MAINIGI:

15 Q. Well, in my hypothetical -- in
16 my hypothetical, Mr. Prevoznik, if the
17 registrant was submitting the excessive
18 purchase reports pursuant to some of the
19 guidelines in this document, the NWDA
20 document, and calling in suspicious orders,
21 that's the execution, right?

22 They were essentially in
23 compliance with at least these guidelines
24 that the NWDA put out, right?

25 MR. FINKELSTEIN: Incomplete

1 hypothetical. Scope.

2 THE WITNESS: I don't have
3 enough information to make that
4 determination because there could
5 be -- it could be just what they're
6 reporting. There could be a whole
7 bunch of things they're not reporting
8 to us.

9 So it goes back to these are --
10 these are the orders that they did
11 report, and these are the orders they
12 did not report, which is essentially
13 why a lot of -- we took enforcement
14 actions on quite a few of these
15 distributors because they were not
16 reporting.

17 So it's only based on what
18 they're reporting to us.

19 QUESTIONS BY MS. MAINIGI:

20 Q. Operationally, however, having
21 a two-tier system in place that includes the
22 excessive purchase reports and then the
23 reporting separately of suspicious orders,
24 operationally in this time period, in the
25 late '90s, that was a system that certainly

1 seemed to make sense to the DEA, correct?

2 MR. FINKELSTEIN: Foundation.

3 THE WITNESS: I think it made
4 sense in terms of the -- at this point
5 we were in -- we were dealing with the
6 meth situation. We were -- and I
7 think I believe I testified to this,
8 that this was more -- at this point
9 this was more of a regional issue.

10 With the on -- with the
11 Internet and things like that where it
12 became a national thing, that's when
13 it was -- that's when orders were
14 clearly not being reported to us.

15 QUESTIONS BY MS. MAINIGI:

16 Q. So my question was a little bit
17 different, right?

18 The structure itself for the
19 late -- that was in place in the late '90s,
20 as outlined by the NWDA suspicious order
21 monitoring system document, that was a system
22 that the DEA thought worked for that time
23 period, correct?

24 MR. FINKELSTEIN: Foundation.

25 THE WITNESS: I think they were

1 leaving it up to the -- to the
2 registrant to do that, because it --
3 in here it's with the -- the number 9,
4 single suspicious order, we determined
5 orders to mean prior to shipment. So
6 it's incumbent upon that registrant.

7 So this is -- this is a
8 whole -- this is a wholesaler
9 association, so its members are going
10 to put this into -- implement it into
11 their system. So if they're following
12 what they're supposed to be doing,
13 then you would hope that it was
14 identifying the suspicious orders as
15 they should have.

16 QUESTIONS BY MS. MAINIGI:

17 Q. Well, let's take a look. We
18 remember Mr. Gitchel, right? Let's take a
19 look at what he wrote.

20 And I think we've got a couple
21 of letters of his attached that relate to
22 this system.

23 So if you take a look at the
24 very last page, page 11, Mr. Gitchel, who at
25 that point was -- what was his role?

1 A. He was the IP chief over
2 operations, diversion operations.

3 Q. So he was the top dog, right,
4 in diversion at DEA?

5 A. Just over operations.

6 Q. And he was communicating with a
7 lot of people during this time period, right?
8 We've seen a few of his letters?

9 A. Yes.

10 Q. Okay. And if you take a look
11 at the letter which is on page 11, he writes
12 a letter to Ronald Streck of the National
13 Wholesale Druggists' Association, right?

14 A. Yes.

15 Q. Okay. And did you review this
16 letter in preparation for your deposition
17 here today?

18 A. Yes. In the past I did, yes.

19 Q. Okay. So you're familiar with
20 this letter?

21 A. (Witness nods head.)

22 Q. Can you read -- do you see a
23 sentence that begins with "this system" in
24 the middle of the first paragraph?

25 A. "This system as proposed will

1 test the reporting" -- will test or meet --
2 "will meet the reporting requirements of 21
3 CFR 1301.74(b) ."

4 Q. So what does that mean to you?

5 MR. FINKELSTEIN: Calls for
6 speculation.

7 THE WITNESS: I'm not sure what
8 he's saying, because the next two
9 sentences below that are -- he's --

10 QUESTIONS BY MS. MAINIGI:

11 Q. Well, what's he saying in this
12 sentence?

13 MR. FINKELSTEIN: Let the
14 witness finish his answer.

15 THE WITNESS: The next two
16 sentences after that are talking about
17 the after-the-fact sales, and it
18 doesn't relieve the registrant from
19 the responsibility of reporting
20 excessive or suspicious orders.

21 So -- and he clearly, again,
22 reiterates what I've been saying.
23 DEA's interpreted orders to mean prior
24 to shipment.

25

1 QUESTIONS BY MS. MAINIGI:

2 Q. Okay. So we just went over
3 this system that the DEA obviously had input
4 into that included two components, right?

5 A. Yes.

6 Q. And the two components -- what
7 was the first component?

8 A. It was the after sales.

9 Q. Okay. So the excessive
10 purchase, right?

11 A. Yes.

12 Q. What was the second component?

13 A. The -- let me check. The
14 suspicious orders.

15 Q. Right.

16 So those are the two components
17 of the NWDA system, right?

18 A. Yes.

19 Q. And the sentences that he's got
20 after the one I asked you to read, he's
21 essentially saying, doing the first doesn't
22 relieve you of the obligation to do the
23 second, right?

24 A. Correct.

25 Q. Okay. So read that sentence to

1 me again that begins with "this system."

2 A. "This system, as proposed, will
3 meet the reporting requirements of 21 CFR
4 1301.74."

5 Q. And what is 1301.74(b) of 21
6 CFR?

7 A. Suspicious orders.

8 Q. Okay. So Mr. Gitchel, who's
9 acting chief of diversion operations, is
10 saying in this letter that this two-component
11 system that we've been discussing, as
12 proposed, will meet the reporting
13 requirements of suspicious orders, correct?

14 A. That's what it says.

15 Q. And so a distributor --

16 MR. FINKELSTEIN: I signaled
17 ten minutes remaining to the witness.

18 QUESTIONS BY MS. MAINIGI:

19 Q. A distributor, Mr. Prevoznik,
20 who in that time period followed this system
21 that NWDA proposed, their system, at least,
22 would be in compliance with 21 CFR
23 1301.74(b), correct?

24 MR. FINKELSTEIN: Incomplete
25 hypothetical.

1 THE WITNESS: Yes, but this
2 date is 1984. You've been asking me
3 1996 to 2006, so -- so, yeah, 1984.

4 QUESTIONS BY MS. MAINIGI:

5 Q. Do you -- are you aware of any
6 communication by Mr. Gitchel subsequently
7 that overruled his statements?

8 MR. FINKELSTEIN: Scope.

9 THE WITNESS: Not to my
10 knowledge.

11 QUESTIONS BY MS. MAINIGI:

12 Q. Now, in this letter that
13 Mr. Gitchel wrote, he doesn't say anything
14 about halting shipment of excessive or
15 suspicious orders, right?

16 A. No.

17 Q. Now, the next time there is
18 some sort of communication with the industry
19 in written form, or an industry group in
20 written form, about approaches to suspicious
21 order monitoring are Mr. Rannazzisi's letters
22 in 2006 and 2007, right?

23 MR. FINKELSTEIN: Foundation.

24 THE WITNESS: No, we had -- we
25 had those conferences. I mean, I

1 think we had one from 1987, the one in
2 San Antonio, so we were meeting with
3 manufacturers and distributors.

4 QUESTIONS BY MS. MAINIGI:

5 Q. The one in 2007?

6 A. No. 19 -- it's in here
7 somewhere.

8 Q. Well, just listen to my
9 question, though.

10 A. Sure.

11 Q. So Mr. Gitchel was
12 communicating with a trade group, right?

13 A. Yes.

14 Q. The National Wholesale
15 Druggists' Association, right?

16 A. Yes.

17 Q. And that was a trade group that
18 communicated then with its distributors, its
19 member distributors, right?

20 MR. FINKELSTEIN: Calls for
21 speculation.

22 THE WITNESS: Yes.

23 QUESTIONS BY MS. MAINIGI:

24 Q. And distributor conferences or
25 conferences that DEA has, those are

1 definitely important, but there's no
2 guarantee that you're going to reach every
3 single distributor out there, right?

4 A. No, but I thought you were
5 asking what guidance DEA has given.

6 Q. No.

7 A. Okay.

8 Q. The question that I asked you
9 was: So Mr. Gitchel wrote a communication to
10 the NWDA which theoretically could have been
11 shared with its member distributors, right?

12 MR. FINKELSTEIN: Calls for
13 speculation.

14 THE WITNESS: Yes.

15 QUESTIONS BY MS. MAINIGI:

16 Q. And it gave them some guidance
17 about their suspicious order monitoring
18 system, correct?

19 A. Correct.

20 Q. And next time the DEA issued
21 any sort of guidance, or anything that could
22 be called guidance, in a written form out to
23 all distributors about their suspicious order
24 monitoring systems was in the form of
25 Mr. Rannazzisi's letters in 2006, 2007?

1 MR. FINKELSTEIN: Foundation.

2 THE WITNESS: Yes.

3 QUESTIONS BY MS. MAINIGI:

4 Q. And obviously we had
5 conversations previously about the statements
6 in those letters, right?

7 A. Yes.

8 Q. Now, prior to Mr. Rannazzisi's
9 letters, you all, the DEA, began the
10 distributor initiative, right?

11 MR. FINKELSTEIN: Asked and
12 answered.

13 THE WITNESS: Yes.

14 QUESTIONS BY MS. MAINIGI:

15 Q. And I think you mentioned that
16 some of the earlier distributor initiatives
17 took place in the fall of 2005; is that
18 right?

19 MR. FINKELSTEIN: Asked and
20 answered.

21 THE WITNESS: I actually think
22 it was August. Some of the documents
23 today were August.

24 QUESTIONS BY MS. MAINIGI:

25 Q. Okay. Do you want to find your

1 document? Let's find the Cardinal one.

2 There's a meeting with
3 Cardinal, and you're right, it's August. At
4 least the date of this memo is August 23,
5 2005.

6 A. August 23rd, got it. P23.

7 Q. Perfect. Thank you.

8 Now, you did not attend this
9 meeting with Cardinal Health, right?

10 MR. FINKELSTEIN: Asked and
11 answered.

12 THE WITNESS: No.

13 QUESTIONS BY MS. MAINIGI:

14 Q. Mr. Mapes and Ms. Seeger
15 attended the meeting?

16 A. Yes.

17 Q. And all DEA has at this point
18 in time reflective of what got said or not
19 said at this meeting is this memo and the
20 attached PowerPoint, true?

21 A. Yes.

22 Q. What points were emphasized at
23 this meeting in 2005 versus any meeting that
24 took place in 2009, 2010, you're not in a
25 position to say beyond the documents you have

1 in front of you, correct?

2 A. Correct.

3 Q. Now, look at the last paragraph
4 of this memo. Do you see that Cardinal was
5 requesting that DEA provide them with certain
6 information?

7 A. Yes.

8 Q. Do you know if the DEA ever
9 provided Cardinal with that information it
10 was seeking?

11 MR. FINKELSTEIN: Scope.

12 THE WITNESS: I don't know.

13 MR. FINKELSTEIN: Vague.

14 QUESTIONS BY MS. MAINIGI:

15 Q. Now, do you recall the industry
16 group that represented distributors at some
17 point morphed its name into HDMA, correct?

18 A. Correct.

19 Q. So it went from NWDA to HDMA,
20 right?

21 A. Yeah. I don't know if there
22 was one in between, but, yes.

23 Q. And now I think they're HDA.
24 Does that sound right to you?

25 A. Yeah.

1 Q. I don't know why they keep
2 changing their names.

3 But do you recall that that was
4 a group that continued to want to meet with
5 DEA to continue to give guidance on how to
6 update their suspicious order monitoring
7 systems?

8 MR. FINKELSTEIN: Scope. Calls
9 for speculation.

10 THE WITNESS: Yes.

11 QUESTIONS BY MS. MAINIGI:

12 Q. Do you recall though that
13 within DEA there was an evolution of thought
14 related to dealing with groups like HDMA
15 where, let's say, from 2007 through to 2013
16 DEA did not want to sit down and provide
17 specific guidance or guidelines to the HDMAs
18 of the world as to how to put their
19 suspicious order monitoring systems together?

20 MR. FINKELSTEIN: Scope.
21 Foundation.

22 THE WITNESS: Is that a
23 question?

24 QUESTIONS BY MS. MAINIGI:

25 Q. Yes.

1 A. Can you repeat it?

2 Q. Sure.

3 Do you recall from the time
4 period of about 2007 to 2013, DEA did not
5 want to sit down with HDMA to provide them
6 with guidance or guidelines related to an
7 adequate suspicious order monitoring system?

8 A. Yes.

9 Q. "Yes" meaning they did not want
10 to sit down with HDMA?

11 A. Right.

12 Q. Whereas in the late '90s, we
13 saw that they were willing to sit down with
14 HDMA, right?

15 A. Correct.

16 Q. And sitting down with HDMA or
17 its predecessor organization in the late '90s
18 helped the public, right?

19 MR. FINKELSTEIN: Calls for
20 speculation.

21 QUESTIONS BY MS. MAINIGI:

22 Q. Isn't that what you told me, it
23 helped the public?

24 A. What, by meeting with them?

25 Q. Yes.

1 A. Yes. Well, we hoped that it
2 helped the public, yes. But, again, it's the
3 registrants that have to design the system
4 and operate the system. It's not NWDA, and
5 it's not HDA, and it's not HDMA. It's the
6 registrant, which is why we shifted to that.

7 Q. Okay. You didn't want to sit
8 down with HDMA to help the public?

9 A. No.

10 MR. FINKELSTEIN: Wait. Vague.
11 Argumentative. Mischaracterizes prior
12 testimony.

13 THE WITNESS: No, we sat
14 with -- we did the distributor
15 initiative because of what we saw, and
16 we saw that the registrants needed to
17 be -- have -- to sit down with the
18 registrants, talk to them and go over
19 their own data with them to show the
20 anomalies that are going on, in the
21 hope that they would stop what they
22 were doing.

23 They said they were going to
24 fix it; they didn't fix it. So we
25 weren't going to go to a trade

1 association if the registrant isn't
2 going to fix their own internal system
3 that they have.

4 MR. FINKELSTEIN: One minute,
5 Ms. Mainigi.

6 QUESTIONS BY MS. MAINIGI:

7 Q. With respect to -- you made
8 some reference, and I think you're doing it
9 again, to some failures in the industry. Do
10 you remember that? Failures by the industry
11 to comply.

12 Do you remember having those
13 discussions with Ms. Singer earlier today?

14 A. Yes.

15 Q. Okay. And by "failures in the
16 industry," I assume you're referring to the
17 various legal actions that distributors had
18 with Cardinal, true? Or excuse me, the
19 various legal actions that distributors had
20 with DEA, true?

21 A. Yes.

22 Q. And so various distributors at
23 various points in time entered into legal
24 settlements with the DEA, true?

25 A. True.

1 MR. FINKELSTEIN: We're at
2 2:30, Special Master. I'd ask to go
3 off the record.

4 SPECIAL MASTER COHEN: I think
5 we're done.

6 MS. MAINIGI: Thank you very
7 much, Mr. Prevoznik.

8 VIDEOGRAPHER: All right. This
9 concludes today's deposition. The
10 time is 5:30.

11 (Deposition concluded at 5:30 p.m.)

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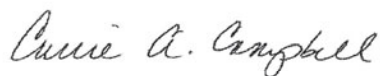
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CERTIFICATE

I, CARRIE A. CAMPBELL, Registered
Diplomate Reporter, Certified Realtime
Reporter and Certified Shorthand Reporter, do
hereby certify that prior to the commencement
of the examination, Thomas Prevotnik was duly
sworn by me to testify to the truth, the
whole truth and nothing but the truth.

I DO FURTHER CERTIFY that the
foregoing is a verbatim transcript of the
testimony as taken stenographically by and
before me at the time, place and on the date
hereinbefore set forth, to the best of my
ability.

I DO FURTHER CERTIFY that I am
neither a relative nor employee nor attorney
nor counsel of any of the parties to this
action, and that I am neither a relative nor
employee of such attorney or counsel, and
that I am not financially interested in the
action.



CARRIE A. CAMPBELL,
NCRA Registered Diplomate Reporter
Certified Realtime Reporter
Notary Public

Dated: May 21, 2019

1 INSTRUCTIONS TO WITNESS

2
3 Please read your deposition over
4 carefully and make any necessary corrections.
5 You should state the reason in the
6 appropriate space on the errata sheet for any
7 corrections that are made.

8 After doing so, please sign the
9 errata sheet and date it. You are signing
10 same subject to the changes you have noted on
11 the errata sheet, which will be attached to
12 your deposition.

13 It is imperative that you return
14 the original errata sheet to the deposing
15 attorney within thirty (30) days of receipt
16 of the deposition transcript by you. If you
17 fail to do so, the deposition transcript may
18 be deemed to be accurate and may be used in
19 court.

ACKNOWLEDGMENT OF DEPONENT

I, _____, do
hereby certify that I have read the foregoing
pages and that the same is a correct
transcription of the answers given by me to
the questions therein propounded, except for
the corrections or changes in form or
substance, if any, noted in the attached
Errata Sheet.

Thomas Prevoznik, Volume III DATE

Subscribed and sworn to before me this
_____ day of _____, 20 _____.

My commission expires: _____

Notary Public

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